Subtitle B—Regulations Relating to Commerce and Foreign Trade

CHAPTER I—BUREAU OF THE CENSUS, DEPARTMENT OF COMMERCE

PART 30—FOREIGN TRADE STATISTICS

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SOURCE: 41 FR 9134, Mar. 3, 1976, unless otherwise noted.

NOTE: The term ''Customs Director'' or ''District Director of Customs'' as used in this Part 30 means the Regional Commissioner of Customs if the transaction is at the port of New York City; the district director of customs if at the headquarters port of a customs district other than New York City; and the customs officer in charge of the port if at a nonheadquarters port.

Subpart A—General Requirements—Exporters

§ 30.1 General statement of requirement for Shipper's Export Declarations.

(a) Shipper's Export Declarations shall be filed by exporters or their agents in accordance with the definitions, specifications, and requirements of these regulations for all commodities, gold and silver, except as specifically exempted herein, shipped as follows:

(1) To foreign countries or areas, including Foreign Trade Zones located therein, (see § 30.58 for exemptions for shipments from the United States to Canada) from any of the following:

(i) The United States, including the 50 States and the District of Columbia.

(ii) Puerto Rico.

(iii) Foreign Trade Zones in the United States or Puerto Rico.

(iv) The Virgin Islands of the United States.

(2) Between nonforeign areas as specified below then:[1]

(i) To Puerto Rico from the United States.

(ii) To the United States from Puerto Rico.

(iii) To the Virgin Islands of the United States from the United States or Puerto Rico.

(b) Shipper's Export Declarations shall be filed for merchandise moving as described above regardless of the method of transportation. Instructions for the filing of Shipper's Export Declarations for vessels, aircraft, railway cars, etc., when sold foreign appear in § 30.33. Exemptions from these requirements and exceptions to some of the provisions of these regulations for particular types of transactions will be found in subparts C and D of this part.

[41 FR 9134, Mar. 3, 1976, as amended at 41 FR 29374, July 16, 1976; 41 FR 42645, Sept. 28, 1976; 50 FR 13017, Apr. 2, 1985; 55 FR 49615, Nov. 30, 1990]

§ 30.2 Related export control requirements.

(a) Under the provisions of the Export Administration Regulations of the Office of Export Administration in the International Trade Administration, U.S. Department of Commerce (15 CFR Parts 368–399),[2] Shipper's Export Declarations are also required for shipments of Merchandise from U.S. Possessions to foreign countries or areas. In these regulations, the term U.S. Possessions includes the Virgin Islands of the United States, Guam Island, American Samoa, Wake Island, Midway Island, and Canton and Enderbury Islands.

(b) For all shipments to foreign countries or areas, the Shipper's Export Declaration is an export control document. In preparing and filing export declarations for shipments to foreign countries and areas, therefore, the shipper must comply with all pertinent export control regulations as well as the requirements of the statistical regulations of this part. For convenience, a few provisions of the Export Administration Regulations and of the Customs

[1] Shipper's Export Declarations are not required for shipments from the United States or Puerto Rico to the United States Possessions, except to the Virgin Islands of the United States, or from a U.S. Possession destined to the United States, Puerto Rico, or another U.S. Possession.

[2] See also the Export Administration Regulations of the Office of Export Administration, which may be purchased from the Government Printing Office or Department of Commerce District Offices.

regulations closely related to statistical requirements have been incorporated in these regulations. Information concerning export control regulations and information concerning agencies other than the Department of Commerce exercising export control authority for particular types of commodities may be obtained from the Office of Export Administration, International Trade Administration, Washington, D.C. 20230, or from Department of Commerce District Offices.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950, Department of Commerce Order No. 35–2A, August 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 47 FR 7213, Feb. 18, 1982]

§30.3 Shipper's Export Declaration forms.

(a) Official forms, or privately printed forms conforming in every respect to the official forms, shall be used in complying with requirements for Shipper's Export Declarations as follows:

(1) Except for shipments for which the Shipper's Export Declaration for In transit Goods (Commerce Form 7513) is required as specified below, the Shipper's Export Declaration shall be prepared on Commerce Form 7525–V or on Commerce Form 7525–V–Alternate (Intermodal). The arrangement of Form 7525–V–Alternate (Intermodal) conforms to and is designed for simultaneous preparation with various other shipping documents commonly used, such as the dock receipt, short form bill of lading, etc. Form 7525–V–Alternate (Intermodal) is acceptable in lieu of Form 7525–V without limitation.

(2) For merchandise shipped in transit through the United States, Puerto Rico, or the Virgin Islands of the United States from one foreign country or area to another, including such merchandise destined from one foreign place to another and transshipped in ports of the United States, Puerto Rico, or the Virgin Islands of the United States, and for foreign merchandise exported from General Order Warehouses, the Shipper's Export Declaration for Intransit Goods (Commerce Form 7513) shall be filed. Form 7513 shall also be filed for merchandise subject to government inspection, examination, or permit arriving from a foreign country which is rejected and exported. (Although Form 7513 provides that it is to be used for foreign merchandise, it should be used also for U.S. merchandise which after having been exported has been returned to or through the United States and is again being exported under any of the conditions described in this paragraph. Except for rejected merchandise, Form 7513 is not to be used for the reexportation of goods for which entry has been made on Customs Forms 7501 or 7502.)

(b) The Shipper's Export Declaration and the Continuation Sheet[3] to the Shipper's Export Declaration (both forms designated Commerce Form 7525–V), and the Shipper's Export Declaration for In-transit Goods (Commerce Form 7513) may be purchased for a nominal price from Customs Directors, Department of Commerce District Offices, and the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, or they may be privately printed. Supplies of the Alternate Intermodal Shipper's Export Declaration and the Continuation Sheet to the Alternate Intermodal Shipper's Export Declaration are not available from Government sales offices but must be privately printed. Sample official Alternate Intermodal Forms and their Continuation Sheets may be obtained from the Foreign Trade Division, Bureau of the Census, Washington, D.C. 20233. Privately printed Shipper's Export Declaration forms must conform strictly to the respective official form in size, wording, color, quality (weight of paper stock), and arrangement, including the Office of Management and Budget approval number printed in the upper-right hand corner of the face of form. The quality (weight) of paper stock used in printing the Shipper's Export Declaration form is not less than 16 nor more than 20 pounds commercial substance. Occasional shippers may obtain copies of Shipper's Export Declarations free of charge from local Customs Directors, Post Offices, and Department of Commerce District Offices.

[3] See §30.10 for instructions as to use of the continuations Sheet.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950, Department of Commerce Order No. 35–2A, August 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 47 FR 29829, July 9, 1982; 50 FR 23402, June 4, 1985]

§ 30.4 Preparation and signature of Shipper's Export Declarations.

(a) The Shipper's Export Declaration shall be prepared and signed by the shipper, owner, or consignor, or his properly authorized agent. For shipments to foreign countries, if the Shipper's Export Declaration is prepared by an agent his authority to sign such declaration shall be in the form of a properly executed power of attorney, signed by the shipper, owner, or consignor, or in the less formal written authorization printed on the export declaration. The power-of-attorney shall be on file in the agent's office and available for inspection on demand. In every event the data required in the Shipper's Export Declaration shall be complete and correct and shall be based on personal knowledge of the facts stated, or on invoices or information furnished by the principal. Exporters who authorize the preparation of their export declarations by an agent shall provide the agent with information for this purpose which will in every respect meet the specifications in §30.7. Particular attention is called to the fact that invoices and other commercial documents furnished to the agent for other purposes may not necessarily contain all of the particular types of information needed for the preparation of the export declaration, and special arrangements should be made so that the information needed for the export declaration is noted upon or accompanies the commercial documents furnished to the agent, if he is to prepare the Shipper's Export Declaration.

(b) Shipper's Export Declarations shall be typewritten or prepared in ink or other permanent medium (except indelible pencil). The use of ditto, hectograph, or other duplicating process, as well as the overprinting of selected items of information, is acceptable.

(c) All copies of the Shipper's Export Declaration shall contain all of the information called for in the signature space as to name of firm, address, name of signer, capacity of signer, etc. The original Shipper's Export Declaration shall be signed in ink, but signature of other copies is not required. The use of signature stamps is acceptable as signature in ink. A duly signed legible carbon or other copy of the export declaration is acceptable as an ''original'' of the Shipper's Export Declaration.

§ 30.5 Number of copies of Shipper's Export Declaration required.

(a) Except as provided elsewhere in these regulations the Shipper's Export Declaration shall be delivered to the carrier or postmasters, as specified in §§30.12 and 30.15, in the following number of copies:

(1) In duplicate for shipments, except by mail, destined to all foreign countries except Canada.

(2) One copy only for shipments to Canada (see §30.58 for exemption for shipments from the United States to Canada) and nonforeign areas.

(3) One copy only for mail shipments to all destinations.

(b) In addition to the standard requirements set forth in paragraph (a) of this section, additional copies of Shipper's Export Declarations may be required for export control purposes by the regulations of the Office of Export Administration or other Government agencies or in particular circumstances by the Customs Director or by the postmaster.

[41 FR 9134, Mar. 3, 1976, as amended at 55 FR 49615, Nov. 30, 1990]

§ 30.6 Requirements as to separate Shipper's Export Declarations.

Except as specifically provided in subpart C, a separate Shipper's Export Declaration (in the required number of copies—see §30.5) is required for each shipment (consisting of one or more kinds of merchandise) from one consignor to one consignee on a single carrier. In addition, more than one declaration is required for an individual shipment as follows:

(a) For consignments by rail, truck, or other vehicle, requiring more than one rail car, truck, or other vehicle, a separate export declaration is required for the merchandise carried in each such rail car, truck, or other vehicle.

However, Customs Directors are authorized to waive this requirement where multiple car shipments are made under a single bill of lading or other loading document and are cleared simultaneously.

(b) [Reserved]

[41 FR 9134, Mar. 3, 1976, as amended at 55 FR 47049, Nov. 9, 1990]

§30.7 Information required on Shipper's Export Declarations.

The following information shall be furnished in the appropriate spaces provided on the Shipper's Export Declaration and shall conform to the requirements set forth in this section. (See §30.92 for information as to the statistical classification Schedules B, C—E, and D referred to in this section. Also, see §30.8 for information required on Form 7513 in addition to these requirements.)

(a) *Port of export.* The name of the U.S. Customs port of exportation shall be entered in terms of Schedule D, *Classification of Customs Districts and Ports.* (See §30.20(c) for definition of port of exportation.) For shipments by mail, the name of the Post Office where the package is mailed shall be inserted in the space for U.S. port of export.

(b) *Method of transportation.* Except on Commerce Form 7513, the method of transportation by which the goods are exported (or shipped to a nonforeign area where the declaration covers such a shipment) i.e., vessel (including ferry), air, or other, shall be indicated by check mark in the appropriate space. For shipments by means of transportation other than vessel or air the specific method of transportation (rail, truck, pipeline, etc.) used should be entered. ''Other'' should be checked for exported aircraft being flown away, vessels exported under their own power or afloat, or for other vehicles exported other than aboard another carrier, and the manner in which exported should be specified; e.g., ''flown away,'' ''in tow,'' etc.

(c) *Exporting carrier.* Information concerning the specific exporting carrier shall be reported as follows:

(1) For shipments by vessel, the name and flag nationality of the ship and the number or name of the pier at which the goods were laden shall be shown.

(2) For shipments by air, the name of the airline shall be reported.

(3) For shipments by other than vessel or air, the carrier shall be identified by name and number or other available designation.

In all cases, the information shall be furnished as to the carrier which transports the merchandise to a foreign country or to an ultimate destination in a nonforeign area, and not as to a different carrier which may have transported the goods to the seaport, airport, or border port of export for final shipment.

(d) *Name of exporter and exporter's Employer Identification Number*—(1) *Name of exporter.* In general, the exporter named on the Shipper's Export Declaration shall be the principal or seller in the export transaction. For exports moving under validated license, the exporter named on the Shipper's Export Declaration shall be the licensee named on the validated export license. The address of the exporter (number, street, place, state) shall also be shown. (On Form 7513, if an authorized agent is representing the exporter, the name of the exporter as defined herein should be shown on the line labeled ''For account of'' where ''Principal or seller'' is indicated below the line on the form.)

(2) *Exporter's Employer Identification Number.* Exporters (or their agents shall report the exporter's Internal Revenue Service Employer Identification Number (EIN). If no internal Revenue Service EIN has been assigned, the exporter's Social Security Number (SSN), preceded by the symbol ''SS,'' should be reported. The exporter's SSN shall be reported if, and only if, no Internal Revenue EIN has been assigned to the exporter. If neither an Internal Revenue Service EIN nor an SSN has been assigned, for example, in case of a foreign entity as the exporter, the EIN or SSN reporting requirement does not apply.

(e) *Agent of exporter* (*forwarding agent*). The name and address of the duly authorized forwarding agent (if any) of the exporter shall be stated. (See §30.4.) (On Form 7513, the information as to agent (if any) should be shown on the line labeled ''Exporter,''

where ''Actual shipper or agent'' is indicated below the line on the form.)

(f) *Ultimate consignee.* The name and address (place, country) of the ultimate consignee whether by sale in the United States or abroad or by consignment shall be stated on the export declaration. For exports to foreign countries, the ultimate consignee shall be the same person so designated in the validated export license or authorized to be ultimate consignee under the applicable general license in conformity with Export Administration Regulations.

(g) *Intermediate consignee.* The name and address of the intermediate consignee (if any) shall be stated. For exports to foreign countries, the intermediate consignee shall be the person named as such in the validated export license or authorized to act as such under the applicable general license and in conformity with the Export Administration Regulations. If there is no intermediate consignee, the word ''none'' shall be entered on the Shipper's Export Declaration. (On Form 7513 the name and address of the intermediate consignee (if any) in a foreign country must be shown below the description of commodities across columns 1 through 6.)

(h) *Foreign port of unloading.* For shipments by vessel and by air the foreign port and country of unloading (i.e., the foreign port and country at which the merchandise will be unlad-en from the exporting carrier) shall be shown on the Shipper's Export Declaration in addition to the country of ultimate destination. The reporting of ''optional'' ports of unloading is not permissible except as provided in the Export Administration Regulations.[4] Where optional ports of unloading are named on the Shipper's Export Declaration under the permissible conditions, a photocopy, carbon, or other legible copy of the originally filed Shipper's Export Declaration indicating the actual port of unloading shall be filed by the exporter or his agent with the Customs Director as soon as the actual port of unloading is known to the exporter. (See §30.16 of these regulations.) Information as to port of unloading is required for shipments by vessel and air only.

(i) *Country of destination.* Country of destination shall be reported on the Shipper's Export Declaration in terms of the names designated in Schedule C–E, *Classification of Country and Territory Designations for U.S. Export Statistics,* as follows:

(1) For shipments under validated export licenses, the country of ultimate destination shown on the export decaration shall conform to the country of ultimate destination as shown on the license.

(2) For shipments not moving under validated export license, the country of ultimate destination as known to the exporter at the time or exportation shall be shown on the export declaration. ''Country of ultimate destination'' means the country in which the goods are to be consumed or further processed or manufactured. The country to which the goods are being shipped is not the country of ultimate destination for purposes of preparing the Shipper's Export Declaration if the exporter has knowledge at the time the goods leave the United States that they are intended for reexport or transshipment in their present form to another known country. For goods shipped to Canada, Panama, Hong Kong, Belgium or The Netherlands for example, special care should be exercised before reporting these countries as the ultimate destination, since these are countries through which merchandise from the United States is frequently transshipped. If the shipper does not know the ultimate destination of the goods, the country of destination to be shown on the export declaration is the last country, as known to the exporter at the time of shipment from the United States, to which the goods are to be shipped in their present form. (For instructions as to the reporting of country of destination for vessels sold or transferred from the United States to foreign ownership, see §30.33.)

(j) *Marks and numbers.* For purposes of identification of the export declaration with the merchandise it covers, the marks, numbers, or other identification shown on the packages should

[4] See Export Administration Regulations. (See footnote 2 to §30.2)

be inserted. This information is not required for shipments by mail inasmuch as the declaration is presented to the Postmaster with the packages being mailed.

(k) *Number and kind of packages.* The number and kind of packages (i.e., boxes, barrels, baskets, bales, etc.) shall be stated.

(l) *Description of commodities and Schedule B number.* The correct commodity number as provided in Schedule B, *Statistical Classification of Domestic and Foreign Commodities Exported from the United States,* shall be entered in the space provided on the Shipper's Export Declaration form, and a description of the merchandise shall be supplied in the ''Description of Commodities'' column in sufficient detail to permit the verification of the Schedule B commodity number. The name of the commodity, in terms which can be identified or associated with the language used in Schedule B (usually the commercial name of the commodity), and any and all characteristics of the commodity which distinguish it from commodities of the same name covered by other Schedule B classifications shall be clearly and fully stated. Careful reference to the Schedule B classification scheme for related commodities as well as for the commodity being shipped is necessary in order to establish which particular characteristics must be stated in the description to permit verification of the correct Schedule B commodity number and to eliminate any question that some other commodity number might apply. A description of commodities in the kind of detail specified above is a separate requirement, and the furnishing of the correct Schedule B commodity number does not relieve the exporter of furnishing, in addition, a complete and accurate commodity description in accordance with this requirement. If the shipment is moving under a validated license, the description shown on the export declaration shall conform with that shown on the validated export license. However, where the description on the license does not state all of the characteristics of the commodity which are needed to completely verify the commodity number, as described above, the missing characteristics, as well as the description shown on the license, shall be stated in the commodity description on the Shipper's Export Declaration.

(m) *Export license number and expiration date* (*or general license symbol*). For exports to foreign countries the export license number and expiration date, or the general license symbol shall be shown below the description of the commodity.

(n) *Net quantity.* Where a unit of quantity is specified in Schedule B for the commodity number in which the item is classified, net quantity is required to be reported in the specified unit, and the unit in which reported should be indicated on the declaration following the net quantity figure. Where the unit of quantity specified in Schedule B is ''No.'' (number), ''Each'' or the abbreviation ''Ea.'' may be indicated on the declaration as the unit of quantity. If no unit of quantity is specified in Schedule B for a numbered classification, but a validated export license for the item specifies a unit of quantity, the net quantity shall be reported on the declaration in terms of the unit of quantity specified in the validated license. If neither Schedule B nor an applicable validated license specifies a unit of quantity for the item, net quantity is not required to be reported, and an ''X'' should be entered in the ''net quantity'' column on the Shipper's Export Declaration. Where Schedule B calls for two units of quantity, net quantity shall be reported in terms of both units. Where the specified unit is in terms of weight (ounces, pounds, etc.) the net quantity should reflect the net weight, exclusive of the weight of barrels, boxes, or other bulky coverings, and exclusive of salt or pickle in the case of salted or pickled fish or meats. *Note, however,* That for a few commodities where ''content lb.,'' ''dry weight,'' or some similar weight unit is specified in Schedule B, the net quantity to be reported on the Shipper's Export Declaration may be less than the net weight. In the expression of net quantities, fractions of one-half unit or upward will be counted as a whole unit, and fractions of less than one-half unit will be ignored, except that where the total net quantity is less than one-half

of the unit prescribed for the commodity in Schedule B ''Less than one-half (unit)'' should be reported. (For example, where the unit for a given commodity is in terms of ''M board feet,'' a net quantity of 8,400 board feet would be reported as ''8 M bd. ft.'' and a net quantity of 900 board feet would be reported as ''1 M bd. ft.''; however, a total net quantity of 450 board feet should not be ignored but should be reported as ''less than one-half M bd. ft.''.)

(o) *Gross (shipping) weight.* In addition to specifying the net quantity in the units required by Schedule B, the gross shipping weight in pounds, including the weight of containers, shall be shown for all shipments by vessel and air. However, for containerized cargo in lift vans, cargo vans, or similar substantial outer containers, the weight of such containers should not be included in the gross weight of the commodities. If gross shipping weight information is not available for individual Schedule B items for the reason that commodities covered by more than one Schedule B number are contained in the same shipping container, approximate shipping weights, estimated as accurately as is practicable, may be shown on the Shipper's Export Declarations for each Schedule B item in the container. The total of the estimated weights must equal the actual shipping weight of the entire container or containers and contents. Gross shipping weight is not required for shipments by mail or for shipments by methods of transportation other than vessel or air.

(p) *''D'' (Domestic) or ''F'' (Foreign).* (1) The export declaration covering exports to foreign countries shall show foreign goods separately from goods of domestic production. Exports of foreign merchandise include those commodities which are the growth, produce, or manufacture of foreign countries which entered the United States, including U.S. Foreign Trade Zones, as imports and which at the time of exportation have undergone no change in form or condition or enhancement in value by further manufacture in the United States, including U.S. Foreign Trade Zones, Puerto Rico, or U.S. Possessions.

(2) Exports of domestic merchandise include those commodities which are the growth, produce, or manufacture of the United States, including U.S. Foreign Trade Zones, Puerto Rico, or U.S. Possessions (including commodities incorporating foreign components), and those articles of foreign origin which have been enhanced in value or changed from the form in which imported by further manufacture or processing in the United States, including U.S. Foreign Trade Zones, Puerto Rico, or U.S. Possessions.

(3) The above distinction between domestic and foreign merchandise is intended only for use in reporting on the Shipper's Export Declaration and is intended for statistical purposes only.

(4) On the Shipper's Export Declaration in the column headed ''Specify 'D' or 'F''', domestic merchandise shall be identified by the designation ''D'' and foreign merchandise shall be identified by the designation ''F.'' On the Shipper's Export Declaration for In-Transit Goods, Form 7513, one of the following statements, whichever is appropriate, shall be shown across the body of the form within columns 1 through 6:

(i) For in-transit shipments of domestic (U.S.) merchandise, ''The merchandise described herein is of the growth, production or manufacture of the United States;'' and

(ii) For in-transit shipments of foreign merchandise, ''The merchandise described herein is of foreign origin.''

(5) *Foreign Military Sales (FMS) indicator.* For any export that represents the delivery of goods or the repair of military equipment under provisions of the FMS program (including those financed under the Foreign Military Finance (FMF) Program), an ''M'' indicator code should be included in Item (16) on Commerce Form 7525–V and in Item (23) on Commerce Form 7525–V–ALT (Intermodal) of the paper SED, with an ''FS'' Export Information Code on the Commodity Line Item Description (CL1) field of the Automated Export System (AES) record layout, and a ''3'' indicator code in field 2 (Type) of the Automated Export Reporting Program (AERP) record layout. This indicator code should be used in lieu of the domestic (D) or foreign (F) indicator code required in those fields on the

SED Form, the AES record, and the AERP record. The FMS indicator code will serve to identify more accurately that segment of U.S. exports that represent FMS deliveries in the U.S. export statistics.

(q) *Value.* (1) In general, the value to be reported on the Shipper's Export Declaration shall be the value at U.S. port of export (selling price or cost if not sold, including inland freight, insurance, and other charges to U.S. port of export) (nearest whole dollar; omit cents figures). Port of Export (Selling price or cost if not sold, including inland freight, insurance and other charges to U.S. port of export) (Nearest whole dollar; omit cents figures).'' ''Selling price'' for goods exported pursuant to sale is the exporter's price to his customer net of any unconditional discounts from list price, but without deducting any discounts which are conditional upon a particular act or performance on the part of the customer. Commissions to be paid by a U.S. exporter to his agent abroad, or to be deducted from the selling price by the exporter's agent abroad should be excluded. For goods shipped on consignment without a sale actually having been made at the time of export, the ''selling price'' to be reported on the Shipper's Export Declaration is the market value at the time of export at the United States port from which exported.

(2) The value reported on the Shippers' Export Declaration shall exclude: The cost of loading on the exporting vessel, aircraft, car or vehicle at the port of exportation; freight, insurance, and any other charges or transportation costs beyond the port of export; and any duties, taxes, or other assessments imposed by foreign countries. The value reported shall include inland or domestic freight or other charges to the seaport, airport, or border port of exportation.

(3) The value to be reported as defined above is (or is equivalent to) an f.a.s. (Free alongside ship) value. Therefore, where goods are sold f.o.b. a U.S. point other than the port of exportation, freight, insurance, and other costs to the border, sea, or airport of exportation shall be added to the selling price (as defined above) for purposes of reporting value on the Shipper's Export Declaration. If the actual amount of such domestic costs is not available, an estimate of the domestic costs shall be added. Where goods are sold at a ''delivered'' price, c.i.f. foreign destination, the cost of loading on the exporting carrier at the port of exportation, if any, and freight, insurance, and other costs beyond the port of exportation should be subtracted from the price for purposes of reporting value on the Shipper's Export Declaration. If the actual amount of such costs is not available, an estimate of the costs should be subtracted. Costs added to or subtracted from the selling price in accordance with the above instructions should not be itemized or shown separately on the Shipper's Export Declaration, but the value reported should be the value after the making of such adjustments, where they are required to arrive at ''value at U.S. port of export.'' In the expression of values in export declarations, fractions of a dollar less than 50 cents should be ignored, and fractions of 50 cents or upward should be counted as $1.

(4) For definitions of the value to be shown on the Shipper's Export Declaration for special types of transactions where the commodities are not being exported pursuant to commercial sales, or where subsidies, government financing or participation, or other unusual conditions are involved, see § 30.30.

(r) *Date of exportation.* Information as to date of exportation is not required to be reported for shipments by vessel or by mail. For other shipments, the date of departure (or date of clearance, if date of departure is not known) shall be shown on the Shipper's Export Declaration as the date of exportation.

(s) *Designation of agent and signature.* For information regarding the use of the space provided on Form 7525–V and 7525–V–Alternate (Intermodal) for authorization of agent, and for requirements as to signature, see § 30.4.

(t) *Point (state) of origin or Foreign Trade Zone number.* (Not required for in-transit merchandise documented on Form 7513.) (1) The state in which the merchandise actually begins its movement in international trade; that is, the state in which the merchandise actually starts its journey to the port of

export. For example, a Shipper's Export Declaration covering merchandise laden aboard a truck at a warehouse in Georgia for transport to Florida for loading onto a vessel for export to a foreign country shall show Georgia as the state of origin. This may not be the state where the merchandise was produced, mined, or grown, or necessarily the state where the exporter is located. The state designation to be shown shall be the U.S. Postal Service's standard two-letter state abbreviation.

(2) For shipments of multistate origin, reported on a single SED, report state of the commodity of the greatest value or, if such information is not known at the time of export, the state in which the commodities are consolidated for export.

(3) For merchandise exported from a U.S. Foreign Trade Zone, the letters ''FTZ'' followed by the Foreign Trade Zone number shall be reported.

(u) *Containerized.* (Not required for in-transit merchandise documented on Form 7513.) This information is required to be shown for vessel shipments only. A containerized shipment is one transported in any size van-type container such as 8′ x 8′ x 20′ or 8′ x 8′ x 40′. Cargo originally booked as *containerized cargo* as well as that placed in containers at the vessel operator's option shall be included.

(v) *Parties to transaction.* (Not required for in-transit merchandise documented on Form 7513.) An export between related parties is one—

(1) From a U.S. person (U.S. exporter) to a foreign business enterprise (foreign consignee) in which at anytime during the fiscal year, the U.S. person owned or controlled, directly or indirectly, 10 percent or more of the voting securities of the foreign enterprise, if an incorporated business enterprise; or an equivalent interest, if an unincorporated business enterprise, including a branch; or

(2) From a U.S. business enterprise (U.S. exporter) to a foreign person (foreign consignee) that, at anytime during the fiscal year, owned or controlled, directly or indirectly, 10 percent or more of the voting securities of the U.S. business enterprise, if an incorporated business enterprise; or an equivalent interest if an unincorporated business enterprise, including a branch.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950; Department of Commerce Organization Order No. 35–2 A, Aug. 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 42 FR 59839, Nov. 22, 1977; 43 FR 50675, Oct. 31, 1978; 43 FR 56030, Nov. 30, 1978; 44 FR 1971, Jan. 8, 1979; 45 FR 29567, May 5, 1980; 47 FR 29829, July 9, 1982; 50 FR 23402, June 4, 1985; 63 FR 41187, Aug. 3, 1998]

§ 30.8 Additional information required on Shipper's Export Declaration for In-Transit Goods (Form 7513).

In addition to the information required under § 30.7, the following information shall be shown on the Shipper's Export Declaration for In-Transit Goods, Form 7513:

(a) *U.S. port of arrival.* The U.S. port at which the merchandise covered by the declaration arrived from a foreign country shall be shown.

(b) *Country from which shipped.* The name of the foreign country where the goods were loaded on the carrier which transported the merchandise to the United States from a foreign country shall be indicated.

(c) *Date of arrival.* The date on which the merchandise arrived in the United States shall be entered.

(d) *Country of origin.* The name of the country of origin as defined in § 30.70(f) shall be indicated.

§ 30.9 Requirements for separation and alignment of items on Shipper's Export Declarations.

For each Schedule B classification (see § 30.7(l)) for which merchandise is included in the shipment, a separate item shall be shown on the Shipper's Export Declaration and the separate description of commodities, shipping weight, ''D'' or ''F'' designation, Schedule B commodity number, net quantity and value for the item shall be correctly aligned horizontally, and clearly distinguishable from information applying to other Schedule B items on the same declaration. However, where merchandise covered by a single Schedule B classification is moving under more than one general license, under more than one validated export license, or under a validated export license which shows two or more listings for

the same Schedule B number, a separate item shall be shown on the Shipper's Export Declaration for each license or for each listing on the license.[5] For merchandise moving under validated license, information required by export control regulations as to export license number and expiration date, and information as to whether the export is a partial or complete shipment against the license, shall be shown immediately below the corresponding description of commodities on the Shipper's Export Declaration. Where two or more items are classified under the same Schedule B number and moving under the same general license, or where no license is required, the quantities, values and shipping weights of such invoice items, wherever practical, should be combined and the information shown on a single horizontal line of the Shipper's Export Declaration. Commodities of U.S. manufacture incorporating foreign components shall be reported under the Schedule B number for the exported commodity, and a separate item shall not be shown for the imported components. If the exporter desires to record the imported components separately on the export declaration for purposes of identification with a temporary import bond, a notation may be made in the ''Description of Commodities'' column as to the imported components that have been incorporated in the exported commodity. In the preparation of the export declaration, shippers shall conform to the line spacing on all copies.

[41 FDR 9134, Mar. 3, 1976, as amended at 50 FR 23403, June 4, 1985]

§30.10 Continuation sheets for Shipper's Export Declaration.

When more horizontal lines than the number provided on the Shipper's Export Declaration form are required to list all of the merchandise covered by the declaration, Continuation Sheets should be utilized.[6] In lieu of official Continuation Sheets, additional copies of the Shipper's Export Declaration form with no portion torn off or removed, may be used as continuation sheets. All continuation sheets shall be numbered in proper sequence and securely stapled to the first sheet, which must be the export declaration itself. Each continuation sheet shall show the Customs port of exportation and the country of ultimate destination for the shipment. The following statement with the blank filled in as appropriate shall be inserted on the last line of the description column of the Shipper's Export Declaration itself:

''This declaration consists of this sheet and No. ——— continuation sheets.''

[41 FDR 9134, Mar. 3, 1976, as amended at 50 FR 23403, June 4, 1985]

§30.11 Authority to require production of documents.

For purposes of verifying the completeness and accuracy of the information reported as required under §§30.7 and 30.8, and for other purposes under the regulations in this part, Customs is authorized to require the owners and operators of exporting carriers, as well as the exporters or their agents, either at the time of exportation or within a period of 3 years subsequent thereto, to produce for inspection or copying shipping documents, invoices, orders, packing lists, correspondence, as well as any other relevant documents and to furnish other information bearing upon a particular exportation. The Bureau of the Census is similarly authorized to require the production of such documents. Customs shall refuse to accept Shipper's Export Declarations containing known errors and omissions, and may require their correction, but acceptance by the Customs Director shall not be construed as evidence that all requirements have been met, and such acceptance shall not relieve the exporter of the responsibility to furnish complete and correct information at a later time if all requirements have in fact not been properly met.

§30.12 Time and place Shipper's Export Declarations required to be presented.

For shipments by mail, the Shipper's Export Declaration as required in §30.1 shall be presented to the postmaster

[5] See §30.6 for prohibition against reporting general license commodities on the same Shipper's Export Declaration with commodities moving under a validated license.

[6] See §30.3(b).

with the packages at the time of mailing. For shipments other than by mail, except as otherwise provided, the Shipper's Export Declaration in the number of copies required by §30.5 shall be delivered to the exporting carrier prior to exportation. It is the duty of the exporter (or his agent) to deliver the required number of copies of the Shipper's Export Declaration to the exporting carrier prior to exportation; failure of the exporter (or his agent) to do so constitutes a violation of the provisions of these regulations, and renders such exporter (or his agent) subject to the penalties provided for in §30.95. For shipments by pipeline, the Shipper's Export Declaration is not required to be presented prior to exportation, and exportation will be permitted upon the understanding that the exporter or his agent, within 4 working days after the end of each calendar month, will file with the Customs Director having jurisdiction for the pipeline, a Shipper's Export Declaration in the number of copies specified in §30.5 to cover exports to each consignee during the calendar month.

§§ 30.13—30.14 [Reserved]

§30.15 Procedure for presentation of declarations covering shipments from an interior point.

For shipments from an interior point, the Shipper's Export Declaration in the number of copies required in §30.5 may be prepared and delivered by the exporter or his agent to the inland carrier to accompany the merchandise to the exporting carrier at the seaport, airport, or border port of exportation, or it may be otherwise delivered directly to the exporting carrier. In either case, the Shipper's Export Declaration must be in the exporting carrier's possession prior to exportation. (See §30.6 for requirements for a separate set of Shipper's Export Declarations, for each car, truck or other vehicle, covering only the merchandise exported in that car, truck, or vehicle.)

§30.16 Corrections to Shipper's Export Declarations.

Exporters (or their agents) shall report corrections, cancellations, or amendments to information reported on Shipper's Export Declarations to the Customs Director at the port of exportation (or, in the case of mail shipments, to the Postmaster at the post office where the shipment was mailed) as soon as the need to such correction, cancellation, or amendment is determined. Such corrections, cancellations, or amendments may be made directly onto the originally filed Shipper's Export Declaration if the originally filed declarations have not already been mailed to the Bureau of the Census. If the originally filed Shipper's Export Declarations have already been mailed to the Bureau of the Census, a photocopy, carbon, or other legible copy of the originally filed Shipper's Export Declaration, on which the incorrect data are neatly lined out and the corrected data entered thereon, shall be promptly filed with the Customs Director at the port of exportation (or, in the case of mail shipments, with the Postmaster at the post office where the shipment was mailed). Such correction copies should have the words ''CORRECTION COPY'' conspicuously shown in the upper right portion of the form. The provisions of this paragraph relating to the reporting of corrections, amendments, or cancellations of information, shall not be construed as a relaxation of the requirements of the laws and regulations pertaining to the preparation and filing of Shipper's Export Declarations.

[42 FR 56604, Oct. 27, 1977]

Subpart B—General Requirements—Exporting Carriers

§30.20 General statement of requirement for the filing of manifests and Shipper's Export Declarations by carriers.

(a) Carriers transporting merchandise from the United States, Puerto Rico, or U.S. Possessions to foreign countries; from the United States or Puerto Rico to the Virgin Islands of the United States; or between Puerto Rico and the United States; shall not be granted clearance, where clearance is required, and shall not depart, where clearance is not required, until manifests (for vessels, aircraft, and rail carriers) and Shipper's Export Declarations have been filed with the Customs Director as specified in paragraphs (b)

through (d) of this section, except as provided in §30.24. Where for reasons beyond the control of the exporting carrier, a given declaration (or declarations) has not been received prior to exportation or departure, and the merchandise has been laden, such carrier shall not as a result of this circumstance be required to off-load the merchandise, or to delay its clearance (where clearance is required) or departure (if clearance is not required). However, the provisions of §30.24 remain applicable.

(b) For carriers transporting merchandise from the United States to Puerto Rico, the complete manifest, as required, and all required Shipper's Export Declarations shall be filed within one business day after arrival, as defined in 19 CFR 4.2(b), with the Customs Director in Puerto Rico, except as provided in §30.24.

(c) Except as otherwise specifically provided, declarations should not be filed at the place where the shipment originates if it is to be transshipped within the United States area before being dispatched to a foreign country or to its final destination in a nonforeign area. This applies to shipments originating in Puerto Rico or the Virgin Islands of the United States being forwarded to the United States for transshipment to another destination, and to shipments originating in the United States and being forwarded to Puerto Rico or the Virgin Islands of the United States for transshipment, as well as to merchandise being transshipped in Customs Districts within the States of the United States. In such cases, the declarations should be filed only with the Customs Director at the actual port of exportation.

(d) For purposes of these regulations, the port of exportation is defined as the Customs port at which or nearest to which the land surface carrier transporting the merchandise crosses the border of the United States into foreign territory, or, in the case of exportation by vessel or air, the Customs port where the merchandise is loaded on the vessel or aircraft which is to carry the merchandise to a foreign country or to a nonforeign area of ultimate destination.

[41 FR 9134, Mar. 3, 1976, as amended at 41 FR 42645, Sept. 28, 1976; 58 FR 41424, Aug. 4, 1993]

§30.21 Requirements for the filing of manifests.

(a) *Vessels.* Vessels transporting merchandise as specified in §30.20 (except vessels exempted by paragraph (d) of this section) shall file a complete Cargo Declaration, Customs Form 1302, or a Cargo Declaration Outward With Commercial Forms, Customs Form 1302–A, either form with copies of bills of lading or equivalent commercial forms relating to all cargo encompassed by the manifest attached thereto. The manifest shall be filed with the Customs Director at the respective ports where the merchandise is laden (for shipments from the United States to Puerto Rico, the manifest shall be filed with the Customs Director in the port where the merchandise is unladen in Puerto Rico), and shall show the destination of the vessel and list all the cargo so laden. For each item of cargo, the manifest shall show a description of the articles, contents, quantities, and values; however, a notation on the Cargo Declaration that values are as stated on the Shipper's Export Declarations, copies of which are attached to such manifest, will be accepted. There shall also be shown for each item of cargo the bill of lading number on the Shipper's Export Declaration covering the item, except that bill of lading numbers are not required on manifests covering cargo destined for Canada or a nonforeign area. If an item on a Cargo Declaration is one for which a Shipper's Export Declaration is not required, a notation shall be inserted on the Cargo Declaration as to the basis for the exemption with a reference to the number of the section in the regulations where the particular exemption is provided. The bills of lading, cargo lists, or other commercial forms must be securely attached to the Cargo Declaration in such manner as to constitute one document; that they are incorporated by suitable reference on the face of the form such as ''Cargo as per bills of lading attached,'' or ''Cargo as per commercial forms attached,'' and that there is shown on the

face of each bill the information required by the Cargo Declaration for the cargo covered by that document. The manifest of vessels (including vessels taking bunker fuel to be laden aboard vessels on the high seas) clearing for foreign countries shall also show the quantities and values of bunker fuel taken aboard at that port for fueling use of the vessel, apart from such quantities as may have been laden on vessels as cargo. The quantity of coal shall be reported in metric tons (2240 pounds), and the quantity of fuel oil shall be reported in barrels of 158.98 liters (42 gallons). Fuel oil shall be described in such manner as to identify diesel oil as distinguished from other types of fuel oil.

(b) *Aircraft.* Aircraft transporting merchandise as specified in §30.20 shall file a complete manifest on Customs Form 7509. Such manifest shall be filed with the Customs Director at the respective ports where the merchandise is laden (for shipments from the United States to Puerto Rico, the manifests shall be filed with the Customs Director in the port where the merchandise is unladen in Puerto Rico) aboard the aircraft that is to carry the merchandise to the foreign country or to its ultimate destination in a nonforeign area, and shall list all the cargo so laden and show, for each item, the air waybill number or marks and numbers on packages, the number of packages, and the nature of the goods, except as otherwise provided in this paragraph (b). In addition, for any item for which a Shipper's Export Declaration is not required under the regulations in this part, a notation as to the basis for the exemption with a reference to the number of the section in this part where the particular exemption is provided, shall be inserted on the manifest, or on the waybill filed in lieu of listing on the manifest. In the case of shipments on an air waybill, a copy of each document may be attached to the cargo manifest, the numbers of such air waybills listed in the body of the manifest, and the statement ''Cargo as per Air Waybills Attached'' noted on the manifest. On direct departures only, for shipments requiring a Shipper's Export Declaration a copy of each declaration may be attached to the cargo manifest. In such case the air waybill numbers of such declarations shall be listed on the cargo manifest in the column for air waybill numbers, and the statement ''Cargo as per SEDs Attached'' noted on the manifest. Under this alternative procedure, any shipments not requiring a Shipper's Export Declaration shall be listed on the manifest, and a notation as to the basis for the exemption with a reference to the number of the section in this part where the particular exemption is provided, shall be shown. For aircraft transporting merchandise between the United States and Puerto Rico, the manifest shall consist of full detail for cargo requiring Shipper's Export Declarations and summary information for cargo exempt for Shipper's Export Declaration requirements. This summary information will include, on a single line, the total number of packages and the total weight, in kilograms, of such exempt shipments. Additionally, the air waybills for all shipments must be available, in the port of arrival or departure in Puerto Rico, for inspection by Customs and/or the Census Bureau.

(c) *Rail carriers.* Rail carriers transporting merchandise as specified in §30.20 shall file a car manifest. Such manifest shall be filed with the Customs Director at the border port of exportation, giving the marks and numbers, the name of the shipper or consignor, description of goods and the destination thereof. The manifest may be a waybill, or a copy thereof, or a copy of the manifest prepared for foreign customs. For any item for which a Shipper's Export Declaration is not required by these regulations, a notation on the manifest, or an oral declaration to the Customs Director, shall be made by the carrier as to the basis for the exemption.

(d) *Carriers not required to file manifests.* These regulations do not require the filing of manifests by carriers other than vessels, aircraft and rail carriers, nor by vessels under 5 net tons engaged in trade with a foreign country otherwise than by sea, nor by vessels specifically exempted from entry by section 441, Tariff Act of 1930, as amended.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950, Department of Commerce Order No. 35–2A, August 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 58 FR 41424, Aug. 4, 1993]

§30.22 Requirements for the filing of Shipper's Export Declarations by departing carriers.

(a) To meet the requirements of §30.20 for the filing of Shipper's Export Declarations, every departing carrier transporting merchandise as specified in §30.20, including vessels, aircraft, rail carriers, trucks and other vehicles, ferries, and every other carrier shall deliver to the Customs Director at the port of exportation (for shipments from the United States to Puerto Rico, at the port of arrival in Puerto Rico), with the manifest of the carrier, if a manifest is required by the regulations in this part, Shipper's Export Declarations prepared and signed by the exporters, or their agents, covering all the cargo for which such Shipper's Export Declarations are required by the regulations in this part.

(b) The exporting carrier shall be responsible for the accuracy of the following items of information (where required) on the declaration: Name of carrier (including flag if vessel carrier), U.S. Customs port of exportation, method of transportation from the United States, foreign port of unloading, the bill of lading or air waybill number, and whether or not containerized. For shipments to Canada exempt from Shipper's Export Declaration filing requirements (See §30.58), the exporting carrier shall enter the U.S. Customs port of exportation and method of transportation from the United States on the bill of lading, air waybill, or other documents that they prepare.

(c) Except as provided in paragraph (d) of this section, when a transportation company finds, prior to the filing of declarations and manifest as provided in paragraph (a) of this section, that due to circumstances beyond the control of the transportation company or to inadvertence, a portion of the merchandise covered by an individual Shipper's Export Declaration has not been exported on the intended carrier, the transportation company shall correct the descriptions and the quantity, value and shipping weight (if any) amounts shown on the declaration to reflect the amount actually exported on the carrier named in the Shipper's Export Declaration. If a short shipment of this type is discovered by the carrier after the Shipper's Export Declaration in question has been delivered to the District Director of Customs, the transportation company will immediately notify the District Director of Customs so that a correction can be made by the Director on all copies of the declaration if it is still in his possession. If the statistical copy of the declaration has been transmitted by the Director to the Bureau of the Census at the time of such notification, the Director will require the exporter (or his agent) to file a ''Correction Copy'' of the originally filed Shipper's Export Declaration as described in §30.16 of these regulations. If the balance of the short-shipped merchandise is subsequently exported, a new Shipper's Export Declaration, complete in all detail, will be required. If the short-shipped merchandise is exported on a carrier of the transportation company named in the original declaration, and if such exportation is made within a reasonable period, the District Director of Customs may accept a declaration executed by such transportation company; otherwise the new declaration shall be executed by the exporter or his agent. In any event, the new declaration shall contain the following statement:

> These commodities or technical data were included, but not shipped, on a Shipper's Export Declaration filed at ———— (Port) on ———— (Date).

(d) When a shipment by air covered by a single Shipper's Export Declaration is divided by the transportation company and exported in more than one aircraft of the transportation company, the ''split shipment'' procedure provided in §30.41 shall be followed by the transportation company in delivering manifests and Shipper's Export Declarations to the District Director of Customs.

(e) Exporting carriers are authorized to amend incorrect shipping weights reported on Shipper's Export Declarations, and to prorate total shipping

weights among the individual commodities, where such carriers are able to do so based upon information in their possession.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950; Department of Commerce Organization Order No. 35–2A, Aug. 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 43 FR 56030, Nov. 30, 1978; 44 FR 1971, Jan. 8, 1979; 55 FR 49615, Nov. 30, 1990; 58 FR 41424, Aug. 4, 1993]

§ 30.23 Requirements for the filing of Shipper's Export Declarations by pipeline carriers.

The operator of a pipeline may transport merchandise to a foreign country without prior filing of Shipper's Export Declarations, on the condition that within 4 days following the end of each calendar month the pipeline operator will deliver to the Customs Director Shipper's Export Declarations prepared by the exporter or his agent covering all exportations through the pipeline to each consignee during the month.

§ 30.24 Clearance or departure of carriers under bond on incomplete manifest or Shipper's Export Declarations.

(a) For purposes of the regulations in this part, except when carriers are transporting merchandise from the United States to Puerto Rico, clearance (where clearance is required) or permission to depart (where clearance is not required) may be granted to any carrier by the Customs Director prior to the filing of a complete manifest as required under the regulations in this part, or prior to the filing by the carrier of all required Shipper's Export Declarations, provided that a bond as specified in paragraph (b) of this section is filed with the Customs Director. The condition of the bond shall be that a complete manifest, where a manifest is required by the regulations in this part and all required Shipper's Export Declarations, shall be filed by the carrier not later than the fourth business day after clearance (where clearance is required) or departure (where clearance is not required) of the carrier except as otherwise specifically provided in paragraphs (a) (1) and (2) of this section. For carriers transporting merchandise from the United States to Puerto Rico, if the complete manifest, as required, and all required Shipper's Export Declarations are not available for filing with the Customs Director in Puerto Rico within one business day after arrival, a bond, as specified in paragraph (b) of this section shall be filed with the Customs Director in Puerto Rico.

(1) For shipments aboard a U.S. flag carrier between the United States and Puerto Rico, or from the United States or Puerto Rico to the Virgin Islands of the United States, the condition of the bond shall be that a complete manifest (where a manifest is required) and all required Shipper's Export Declarations shall be filed by the carrier not later than the seventh business day after departure or in the case of shipments from the United States to Puerto Rico, the seventh business day after arrival.

(2) For rail carriers to Canada, the condition of the bond shall be that the manifest and all required Shipper's Export Declarations shall be filed not later than the 15th business day after departure.

In the event that any required manifest and all required Shipper's Export Declarations are not filed by the carrier within the period provided by the bond, then a penalty of $50 shall be exacted for each day's delinquency beyond the allowed period of 4 days, 7 days, or 15 days, as appropriate; and if the completed manifest, where required, and all required Shipper's Export Declarations are not filed within 3 days following the period of 4 days, 7 days, or 15 days, allowed under the bond, then for each succeeding day of delinquency a penalty of $100 shall be exacted, but no penalty shall exceed $1,000 in total. Remission or mitigation of the penalties provided herein may be granted in those cases where, in the judgment of the administering authority provided in paragraph (b) of this section, the penalties were incurred without willful negligence or fraud, or other circumstances justify a remission or mitigation.

(b) Bonds filed in accordance with the provisions of this § 30.24 may take the form of a single entry bond on Customs Form 7567 in the amount of $1,000 or of a term or blanket bond on Customs Form 7569 in the amount of $10,000 or

such larger amount as the Secretary of the Treasury may prescribe, or in other approved form. Except as provided below in this paragraph, there shall be shown on the bond, or on a separate listing which refers to and is made a part of the bond, a pro forma list of shipments on board the departing carrier for which Shipper's Export Declarations have not been filed with the Customs Director. The list shall show for each such shipment the name of the shipper, the country to which exported, marks and numbers of the packages, the number and kind of packages, a description of the goods and the value (or estimated value). However, where such waiver will not interfere with the ability of the Customs Director to check on performance under the bond, or with the identification of the shipment for purposes of obtaining statistical information in the event of failure of performance under the bond, the Customs Director may waive the requirement for the pro forma list of shipments for which declarations are missing, or may accept a list containing less than the items of information enumerated above. Approval of bonds and administration of the provisions of the regulations in this part relating to performance by carriers under such bonds, including remission and mitigation of penalties incurred by the carriers, are hereby delegated to the Commissioner of Customs or his delegate to be carried out in accordance with the provisions of section 623 of the Tariff Act of 1930, as amended, and the regulations of the U.S. Customs Service issued pursuant thereto.

[41 FR 9134, Mar. 3, 1976, as amended at 58 FR 41425, Aug. 4, 1993]

Subpart C—Special Provisions Applicable Under Particular Circumstances

§30.30 Values for certain types of transactions.

The following special arrangements govern the values to be reported for shipments of the following unusual types:

(a) *Subsidized exports of agricultural products.* Where provision is made for the payment of an export subsidy to the exporter for the exportation of agricultural commodities under a program of the Department of Agriculture, the value required to be shown on the export declaration is the f.a.s. value as defined in §30.7(q), based on the selling price paid by the foreign importer, excluding the amount of the subsidy.

(b) *GSA exports of excess personal property.* For exports of General Services Administration excess personal property, the value to be shown on the Shipper's Export Declaration will be the total of the estimated ''fair value,'' if any, at which the property was transferred to GSA by the holding agency, plus charges, when applicable, to the port of export, such as packing, rehabilitation, inland freight or drayage. The estimated ''fair value'' may be zero, or it may be a percentage of the original or estimated acquisition costs. (Export Declarations for such shipments will bear the notation ''Excess Personal Property, GSA Regulations 1–III, 303.03.'')

§30.31 Identification of certain nonstatistical and other unusual transactions.

In order to enable the Bureau of the Census to make a judgment as to the statistical or other status of certain export transactions, Shipper's Export Declarations covering the following types of transactions should carry a statement beneath the commodity description clearly identifying the transactions as such:

(a) Merchandise exported for repair only, and other temporary exports to be returned to the United States which are not sold and do not enter the trade of the country to which shipped, e.g., merchandise for exhibition (not for exhibition and possible sale), horses or other animals for breeding or grazing, etc.

(b) The return of merchandise previously imported for repair only and other returns to the foreign shipper of temporarily imported merchandise (declared as such on importation) on which no alteration or processing has been performed; e.g., foreign merchandise being returned to the country of origin after importation into the United States for exhibition only.

(c) Shipments of material in connection with construction, maintenance, and related work being done on projects for the U.S. Armed Forces. Equipment and other material shipped for temporary use on such projects and intended for return to the United States should be identified separately from construction material or other goods which will become a part of or which will be consumed in the construction or maintenance work.

§ 30.32 [Reserved]

§ 30.33 Vessels, planes, cargo vans, and other carriers and containers sold foreign.

(a) Vessels, locomotives, rail cars, ferries, trucks, other vehicles, trailers, pallets, cargo vans, lift vans, or similar shipping containers are not considered ''shipped'' in terms of these regulations in this part when they are moving, either loaded or empty, without transfer of ownership or title, in their capacity as carriers of merchandise or as instruments of such carriers, and Shipper's Export Declarations are not required therefor when so moving.

(b) However, Shipper's Export Declarations shall be filed for such items, when moving as merchandise pursuant to sale or other transfer from ownership in the United States to ownership abroad. When a new vessel built in the United States for foreign account clears under a certificate of record (Commerce Form 1316) a Shipper's Export Declaration must be furnished by the agents or prepared by Customs for statistical purposes. If a vessel, car, vehicle, or container, whether in service or newly built or manufactured, is sold or transferred to foreign ownership while in the Customs area of the United States or at a port in such area, Shipper's Export Declarations shall be filed in accordance with the general requirements of the regulations in this part, at the port through or from which the vessel, car, vehicle, or container first leaves the United States after sale or transfer. If the vessel, car, vehicle, or shipping container is outside the Customs area of the United States at the time of sale or transfer to foreign ownership, Shipper's Export Declarations shall be filed at the last port of clearance or departure from the United States prior to sale or transfer. The country of destination to be shown on the Shipper's Export Declaration for vessels sold foreign is the country of new ownership. The country for which the vessel clears, or the country of registry of the vessel, should not be reported as the country of destination on the Shipper's Export Declaration unless such country is the country of new ownership.

§ 30.34 Return of exported cargo to the United States prior to reaching its final destination.

(a) When a vessel carrying cargo which cleared from a port in the U.S. Customs area returns to the U.S. Customs area before it reaches its destination and discharges any or all of its cargo in the United States, the Customs Director at the port of unlading shall notify the Foreign Trade Division, Bureau of the Census, of this fact. The letter of notification shall contain the following information: Name of the carrier, dates of clearance, manifest numbers assigned at the various Customs ports at which cargo was laden and the final disposition of all cargo. If the vessel returns to the port at which the cargo was originally laden, the letter of notification shall also include the bill of lading numbers shown on each export declaration filed at the time of clearance.

(b) For shipments by air where the Shipper's Export Declarations are filed at the port of lading, if it becomes necessary because of an emergency to unload part or all of the cargo at another port in the U.S. Customs area (other than the port in Puerto Rico or U.S. Possession which is its final destination), the Shipper's Export Declarations filed at the port of lading need not be cancelled if the merchandise is reladen on another plane at the second port within a reasonable time and proceeds to its country of destination. If there is unreasonable delay in reloading, the originally filed declarations should be cancelled and new declarations should be filed at the second port of lading. If for any reason, the merchandise remains permanently in the United States, the Customs Director at the first port of lading must be notified

to cancel the Shipper's Export Declarations which have been filed. This provision is not intended as an exception from the requirements of §30.12 as to the place at which Shipper's Export Declarations are required to be filed; it is intended only for cases where an emergency requires an unintended unloading after the requirements of §30.12 have been met.

§§ 30.35—30.36 [Reserved]

§ 30.37 Exceptions from the requirement for reporting complete commodity detail on the Shipper's Export Declaration.

(a) Where it can be determined that particular types of U.S. Government shipments, or shipments for Government projects, are of such nature that they should not be included in the export statistics, and further, where no detriment to the export control program would be involved, special arrangements can sometimes be made to waive compliance with specific portions of the requirements of §30.7 with respect to the reporting of detailed information on the Shipper's. Export Declaration. Such exceptions will be made only upon application by the exporter and specific authorization to the Customs Director and the exporter for the particular project or shipment, approved by both the Bureau of the Census and the Office of Export Administration, and will be conditioned upon a prescribed identification which must appear upon the declarations. The particular types of shipments for which such exceptions may be possible are as follows:

(1) Shipments to a contractor under a Department of Defense or other armed service contract for the construction of facilities for the use of the U.S. armed services.

(2) Temporary exports by or to U.S. Government agencies.

(3) Shipments of supplies and material to contractors in the Panama Canal Zone for the construction and/or maintenance of the Panama Canal Zone and its facilities.

(b) Special exemptions to specific portions of the requirements of §30.7 with respect to the reporting of detailed information on the Shipper's Export Declaration may also be granted by the Bureau of the Census with the concurrence of the Office of Export Administration for certain Department of Defense shipments, or shipments made on behalf of the Department of Defense, to foreign governments under the cash reimbursable provisions of the Mutual Defense Assistance Program (military sales), if and when arrangements have been made for the Bureau of the Census to obtain the desired statistical information other than through the reporting of complete commodity detail on the Shipper's Export Declaration.

§ 30.38 [Reserved]

§ 30.39 Authorization for reporting statistical information other than by means of individual Shipper's Export Declarations filed for each shipment.

(a) A Customs Director, if he finds that no administrative difficulties are involved, may authorize the filing of one Shipper's Export Declaration per month, in lieu of a declaration for each shipment as required by §30.6, for the following types of frequently recurring shipments by air from a single consignor from one U.S. airport to one country of destination and one port of unlading via a single airline:

(1) Newspapers and magazines.

(2) Newsreel films, mats, proofs, etc.

(3) Airline timetables being shipped by the airline.

(4) Shipments of registered carrier stores by a United States or Candian airline to each of its installations or agents abroad which are exported under General License RCS of the Export Administration Regulations set forth in §371.12(d) of this title. Such authorization will be subject to the requirement that a declaration covering all such shipments made during the month named on the declaration will be filed by the consignor with the Customs Director no later than the fifth working day of the month following the month covered, and also except for shipments under paragraph (a)(4) of this section, subject to the requirement that a Continuation Sheet or other attachment filed with the declaration will list the names of the individual consignees and the number of items shipped to each.

(b) In addition to the procedures authorized in paragraph (a) of this section, the Bureau of the Census, with the concurrence of the Office of Export Administration, may, on an individual case basis, authorize exemption from the requirement of § 30.6 that an export declaration be filed for each shipment, the exemption to be conditioned upon the filing, after the close of each month, of a single export declaration or other statistical report, in an approved format including punch cards, computer tapes, etc., covering shipments made during the month to all destinations except countries prohibited by the Export Administration Regulations of the Office of Export Administration (Parts 368–399 of this title),[7] as follows:

(1) Application for permission to file export information on a monthly basis may be made directly to the Foreign Trade Division, Bureau of the Census, Washington, D.C. 20233, with a copy sent to the Office of Export Administration, International Trade Administration, Washington, D.C. 20230.

(2) Authorization will be issued only when in the judgment of the Bureau of the Census complete and accurate information will be available on a monthly basis from the records of the applicant, and where the exemption from the filing of a Shipper's Export Declaration for individual shipments represents a reduction of reporting procedure in the individual case. (In general, these special reporting procedures will be limited to shippers who, on a continuing basis, make at least twenty (20) shipments per month out of an individual port by each of any one or more methods of transportation, and who are able to furnish summary data each month in all the detail required for statistical processing in terms of the various classifications and cross-classifications now required for statistical purposes, such as commodity data by port, by method of transportation and/or by name of carrier.) Where export control is a consideration, such authorizations will be granted when in the judgment of the Office of Export Administration the applicant also has demonstrated that it has established adequate internal operating procedures and has taken other satisfactory safeguards to assure compliance with Export Administration Regulations without government review of individual declarations.

(3)(i) Procedures for clearing individual shipments through Customs without the presentation of a declaration, and the exact type of monthly or other report to be delivered, will be discussed and specifications developed in connection with each application.

(ii) Such authorizations will be subject to the requirement that declarations or other approved summarizations containing the necessary statistical information for all such shipments made during a given month will be submitted no later than the fifth working day of the month following the month of export. Moreover, records must be maintained in such a manner that the Bureau of the Census, the Office of Export Administration, or the U.S. Customs Service may, if desired, verify that a given shipment was, in fact, included in a particular monthly report.

(c) Authorization for the filing of monthly declarations or other summarizations under paragraphs (a) and (b) of this section may be terminated at any time.

(d) Part 386 of the Department of Commerce Export Administration Regulations contains complete information on the requirements of the Office of Export Administration in connection with the granting of authorizations for the filing of monthly summaries of export shipments.

(e) Exporters (or their agents) of merchandise for storage in Canada but ultimately destined for third countries, the specific country of destination being unknown at the time of exportation to Canada, must report statistical information directly to the Bureau of the Census in lieu of filing individual Shipper's Export Declarations for each shipment. The information must be submitted in a format and on a time schedule approved by the Bureau of the Census. The information required will be no more detailed than

[7] Country groups are established and maintained by the Office of Export Administration. See Export Administration Regulations (15 CFR Parts 368–399) for lists of countries included in each country group.

that which would be reported on a Shipper's Export Declaration.

[41 FR 9134, Mar. 3, 1976, as amended at 47 FR 7213, Feb. 18, 1982; 55 FR 49615, Nov. 30, 1990]

§ 30.40 Single declaration for multiple consignees.

As a further exception to the requirements of § 30.6, shipper's are authorized, subject to the approval of the Customs Director, to file one Shipper's Export Declaration (in duplicate) for all shipments, other than those made to U.S. Government agencies, offices, establishments, or representatives of any of these which are laden on one vessel or aircraft and destined to go to one port in Puerto Rico, the Virgin Islands of the United States, or the Canal Zone. For such shipments no consignee information needs to be furnished whether such shipments are made to one or several consignees.

[41 FR 42645, Sept. 28, 1976]

§ 30.41 "Split shipments" by air.

When a shipment by air covered by a single Shipper's Export Declaration is divided by the exporting transportation company at the port where the declaration is filed, and part of the shipment is exported on one aircraft and part on another aircraft of the same transportation company, the following procedure shall apply:

(a) The carrier will deliver the manifest copy of the declaration to the District Director of Customs with the manifest covering the flight on which the first part of the split shipment is exported, and will make no changes on the declaration. However, the manifest will show in the ''number of packages'' column the actual portion of the declared total quantity being carried and will carry a notation to indicate ''Split Shipment.''

(b) On each subsequent manifest covering a flight on which any part of a split shipment is exported, a prominent notation ''SPLIT SHIPMENT'' will be made adjacent to the item on the manifest for ready identification. For the last shipment the notation will read ''SPLIT SHIPMENT, FINAL.''

Each subsequent manifest covering a part of a split shipment shall also show in the ''number of packages'' column only the merchandise carried on that particular flight and a reference to the total amount originally declared for export, e.g., 5 of 11, or 5/11; and immediately following the line showing the portion of the split shipment carried on that flight, a notation will be made showing the air waybill number shown on the original Shipper's Export Declaration and the portions of the originally declared total carried on each previous flight together with the number and date of each such previous flight, e.g., original Shipper's Export Declaration AWB 123; 2 of 11 flight 36A, June 6; 4 of 11, flight 40X, June 10.

(c) Export declarations will not be required for these subsequent shipments.

Subpart D—Exemptions from the Requirements for the Filing of Shipper's Export Declarations

§ 30.50 Procedure for shipments exempt from the requirements for Shipper's Export Declarations.

Except as provided below, where an exemption from the requirement for the filing of a Shipper's Export Declaration is provided in this subpart, a notation describing the basis for the exemption shall be made on the bill of lading, air waybill, or other loading document for carrier use, with a reference to the number of the section in this part where the particular exemption is provided so that the carrier at the time of lading, and the Customs Director at the time of exportation, may verify that no declaration is required. If none of the above named documents is used, the person transporting the merchandise must be prepared to identify to the Customs Director at the port of exportation, at the time of exportation but prior to departure, any merchandise which is exempt from the requirement for the filing of a Shippers' Export Declaration and explain to the Customs Director the basis for the exemption. Where shipments are exempt from the requirement for Shipper's Export Declarations on the basis of value and destination, the appearance of the value and destination on the bill of lading, air waybill, or other loading document for carrier use, shall be acceptable as evidence of the exemption, and no reference need be made to

the particular section of these regulations where the exemption is provided.

§ 30.51 Government shipments not generally exempt.

Except as provided below in this subpart, Shipper's Export Declarations are required for exports by or to U.S. Government agencies, whether or not shipped on a Government bill of lading. No general exemption is provided for Government shipments, as such.

§ 30.52 Special exemptions for shipments to the U.S. armed services.

Shipper's Export Declarations are not required for the following types of shipments to the U.S. armed services:

(a) All commodities, whether shipped commercially or through government channels, consigned to the U.S. armed services for their exclusive use, including shipments to armed services exchange systems. (This exemption does not apply to shipments which are for the ultimate use of the U.S. armed services but which are not consigned to the U.S. armed services. However, special exceptions to the requirements of these regulations which may in some circumstances apply to shipments for the ultimate use of the U.S. armed services but not so consigned are provided in § 30.37.)

(b) Department of Defense Military Assistance Program Grant-Aid shipments being transported as Department of Defense cargo under the provisions of Customs Circular Letters VES–5–MA, March 8, 1954, (MC 133), VES–5–MA, June 17, 1954 (MC 133 S.1), VES–5–MA, May 24, 1956 (MC 133 S.2) and RES–20–MC, January 25, 1960 (CC 76). Under arrangements with the Department of Defense, information on these shipments for inclusion in U.S. export statistics will be furnished directly to the Bureau of the Census by the Department of Defense. This exception from the filing of Shipper's Export Declarations does not apply to Military Assistance Program Grant-Aid shipments to which a foreign government has taken title before exportation or to any Grant-Aid Military-Aid Program shipment moving in any manner other than as Department of Defense cargo. (See § 30.37 for possible exceptions to the full reporting requirements of § 30.7 for certain military sales shipments not exempt from the requirement for the Shipper's Export Declaration.)

§ 30.53 Special exemptions for certain shipments to U.S. Government agencies and employees.

Shipper's Export Declarations are not required for the following types of shipments to U.S. Government agencies and employees:

(a) Office furniture, office equipment, and office supplies shipped to and for the exclusive use of U.S. Government offices.

(b) Household goods and personal property shipped to and for the exclusive and personal use of U.S. Government employees.

(c) Food, medicines, and related items and other commissary supplies shipped to U.S. Government offices or employees for the exclusive use of such employees, or to U.S. Government employee cooperative or other associations for subsequent sale or other distribution to such employees.

(d) Books, maps, charts, pamphlets, and similar articles shipped by U.S. Government offices to U.S. or foreign libraries, government establishments or similar institutions.

(e) All commodities shipped to and for the exclusive use of the Panama Canal Zone Government or the Panama Canal Company.

§ 30.54 Special exemptions for mail shipments.

Shipper's Export Declaration are not required for the following kinds of shipments by mail:

(a) Shipments (except shipments requiring a validated export license) where one or more of the following conditions are present:

(1) Either the consignor or the consignee is not a business concern.

(2) The shipment is valued at $500 or under.

(3) The goods are not mailed for commercial consideration.

(b) Technical data regardless of value, licensing requirements, and the other criteria set forth in paragraph (a) of this section.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950, Department of Commerce Order No. 35–2A, Aug. 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 44 FR 38833, July 3, 1979]

§30.55 Miscellaneous exemptions.

Shipper's Export Declarations are not required for the following kinds of shipments:

(a) Diplomatic pouches and their contents.

(b) Human remains and accompanying appropriate receptacles and flowers.

(c) Shipments from one point in the United States to another thereof by routes passing through Mexico.

(d) Shipments from one point in Mexico to another point thereof by routes through the United States.

(e) Shipments, other than by vessel, or merchandise for which no validated export licenses are required, transported in bond through the United States, and exported from another U.S. port, or transshipped and exported directly from the port of arrival.

(f) Shipments to foreign libraries, government establishments, or similar institutions, as provided in §30.53(d).

(g) Shipments of single gift parcels as encompassed by Office of Export Administration General License GIFT.

(h) Except as noted in paragraph (h)(2) of this section and for exports to Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria, shipments of commodities where the value of the commodities, shipped from one exporter to one consignee on a single exporting carrier, classified under an individual Schedule B number, is $2,500 or less. For Cuba, Iran, Iraq, Libya, North Korea, Sudan and Syria, a SED is required regardless of the value of the shipment.

(1) This exemption applies to individual Schedule B commodity numbers regardless of the total shipment value. In instances where a shipment contains a mixture of individual Schedule B commodity numbers valued $2,500 or less and individual Schedule B commodity numbers valued over $2,500, only those commodity numbers valued $2,500 or more need be reported on a Shipper's Export Declaration.

(2) This exemption does not apply to shipments:

(i) Exported through the U.S. Postal Service (See §30.54).

(ii) Requiring a Department of Commerce validated export license (Individual, Project, Distribution, and Service Supply) (15 CFR, parts 772 and 773).

(iii) Requiring a Department of State, Office of Defense Trade Controls export license under the International Traffic in Arms Regulations (ITAR–22 CFR, parts 121–130).

(iv) Subject to the ITAR but exempt from license requirements.

(v) Requiring a Department of Justice, Drug Enforcement Administration export permit (21 CFR, part 1312).

This exemption shall be conditioned upon the filing of such reports as the Bureau of the Census shall periodically require to compile statistics on $2500 and under shipments.

(i) Shipments of interplant correspondence, executed invoices and other documents, and other shipments of company business records from a U.S. firm to its subsidiary or affiliate.

(j) Shipments of pets as baggage, accompanied or unaccompanied, of persons leaving the United States, including members of crews on vessels and aircraft.

(k) Shipments for use in connection with NASA tracking systems under Office of Export Administration Project License DL–5355–S.

(l) Shipments of aircraft parts and equipment, and food, saloon, slop chest, and related stores, provisions, and supplies for use on aircraft, by a U.S. airline to its own installations, aircraft, and agents abroad, under Department of Commerce, Office of Export Administration General License RCS.

(m) Shipments for use in connection with NOAA operations under the Office of Export Administration General License G–NOAA.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950, Department of Commerce Order No. 35–2A, Aug. 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 47 FR 7214, Feb. 18, 1982; 55 FR 21187, May 23, 1990; 55 FR 49615, Nov. 30, 1990; 63 FR 45697, Aug. 27, 1998]

§ 30.56 Conditional exemptions.

Shipper's Export Declarations are not required for the following classes of commodities when they are not shipped as cargo under a bill of lading or an air waybill and do not require a validated export license, but the exporter should be prepared to make oral declaration to the Customs Director, if required:

(a) Baggage and personal effects, accompanied or unaccompanied, of persons leaving the United States, including members of crews on vessels and aircraft, such as:

(1) Usual and reasonable kinds and quantities of wearing apparel, articles of personal adornment, toilet articles, medicinal supplies, food, souvenirs, games, and similar personal effects and their containers.

(2) Usual and reasonable kinds and quantities of furniture, household effects, household furnishings, and their containers.

(3) Usual and reasonable kinds and quantities of vehicles, such as passenger cars, station wagons, trucks, trailers, motorcycles, bicycles, tricycles, perambulators, and their containers.

Provided, That the above-indicated baggage and personal effects (i) shall include only such articles as are owned by such person or members of his immediate family; (ii) shall be in his possession at the time of or prior to his departure from the United States for the foreign country; (iii) are necessary and appropriate for the use of such person or his immediate family; (iv) are intended for his use or the use of his immediate family; and (v) are not intended for sale.

(b) Tools of trade are usual and reasonable kinds and quantities of commodities and software, and their containers, that are intended for use by individual exporters or by employees or representatives of the exporting company in furthering the enterprises and undertakings of the exporter abroad. Commodities and software eligible for this exemption are those that do not normally require an export license or that are exported without a license as specified in 15 CFR 740.9 of the EAR (15 CFR chapter VII, subchapter C) and are subject to the following provisions:

(1) Are owned by the individual exporter or exporting company;

(2) Accompany the individual exporter, employee or representative of the exporting company;

(3) Are necessary and appropriate and intended for the personal and/or business use of the individual exporter, employee or representative of the company or business;

(4) Are not for sale; and

(5) Are returned to the United States no later than one year from the date of export.

(c) Carriers' stores (including merchandise carried in ships aboard carriers for sale to passengers), supplies, and equipment for departing vessels, planes, or other carriers, including usual and reasonable kinds and quantities of bunker fuel, deck engine and steward department stores, provisions and supplies, medicinal and surgical supplies, food stores, slop chest articles, and saloon stores or supplies for use or consumption on board and not intended for unlading in a foreign country, and including usual and reasonable kinds and quantities of equipment and spare parts for permanent use on the carrier when necessary for proper operation of such carrier and not intended for unlading in a foreign country. Hay, straw, feed, and other appurtenances necessary to the care and feeding of livestock while enroute to a foreign destination are considered part of carriers' stores of carrying vessels, trains, planes, etc.

(d) Dunnage of usual and reasonable kinds and quantities necessary and appropriate to stow or secure cargo on the outgoing or any immediate return voyage of an exporting carrier, when exported solely for use as dunnage and not intended for unlading in a foreign country.

[41 FR 9134, Mar. 3, 1976, as amended at 62 FR 49437, Sept. 22, 1997]

§ 30.57 Information on export declarations for shipments of types of goods covered by § 30.56 not conditionally exempt.

(a) In those cases where Shipper's Export Declarations are required for articles enumerated in § 30.56 (a) through (d) only by virtue of their being shipped under a bill of lading or an air

waybill (no validated license is required) the export declaration should clearly show in the column for commodity description, in lieu of the complete commodity description a statement that the shipment consists of baggage, personal effects, household effects, ship's stores, crew's effects, or as appropriate. In such cases, Schedule B commodity numbers should not be shown on the declarations.

(b) In those cases where the articles enumerated in §30.56 (a) through (d) require a validated export license (whether or not shipped under a bill of lading or an air waybill) the Shipper's Export Declaration must identify the shipment as baggage, personal effects, etc., and must contain all the information normally required for any exportation made under a validated export license, i.e. complete commodity description, license number, Schedule B number, quantity, value, etc.

§30.58 Exemption for shipments from the United States to Canada.

(a) Except as noted in paragraph (c) of this section, shipments originating in the United States where the country of ultimate destination (see §30.7(i)) is Canada are exempt from the Shipper's Export Declaration requirements of this part. This exemption also applies to shipments from one point in the United States or Canada to another point thereof by routes passing through the other country.

(b) The Harbor Maintenance Fee applies to shipments by vessel exempt from Shipper's Export Declaration requirements by virtue of being destined to Canada.

(c) This exemption does not apply to the following shipments: (The Bureau of the Census also reserves the right to reinstate the Shipper's Export Declaration requirements of this part in specific instances for the purpose of ensuring statistical accuracy.)

(1) Requiring a Department of Commerce validated export license.

(2) Requiring a Department of State, Office of Defense Trade Controls, export license under the International Traffic in Arms Regulations (ITAR–22 CFR parts 121–130).

(3) Subject to the ITAR but exempt from license requirements.

(4) Requiring a Department of Justice, Drug Enforcement Administration, export declaration (21 CFR part 1313).

(5) For storage in Canada but ultimately destined for third countries, the specific country of destination being unknown at the time of export to Canada (see §30.39 for reporting requirements).

[55 FR 49615, Nov. 30, 1990]

Subpart E—General Requirements—Importers

§30.70 Statistical information required on import entries.

Information for statistics on merchandise entering the United States from foreign countries, U.S. Foreign Trade Zones, and from the Virgin Islands of the United States, and other nonforeign areas (except Puerto Rico), is required to be reported by importers on the following Customs entry and withdrawal forms respectively required by U.S. Customs regulations for individual transactions: Custom Forms 7500, 7501, 7502, 7505, 7506, 7519, 7521, and 7535, and on Customs Form 7512 when used as an intransit entry to document immediate exportation or transportation and exportation. The following items of information for statistics shall be reported on the respective forms:[9]

(a) *District and port code.* (All forms.) The Customs district code number and the port code number (as shown in Schedule D, *Classification of Customs Districts and Ports*) for the Customs port of entry or filing shall be supplied. (Where Customs does not require that the District and Port codes be inserted by importers, the codes will be filled in by Customs so that all entries and withdrawals received by the Bureau of the Census will bear these codes.)

(b) *Importing vessel or carrier.* (Not required for merchandise entering U.S. Customs territory from U.S. Foreign

[9] The information required for statistical purposes is in most cases also required by Customs regulations for other purposes. (See §30.80 for special reporting instructions for merchandise entering United States Customs Territory from United States Foreign Trade Zones.)

Trade Zones.) (1) (Customs Forms 7501, 7502, 7512, and 7521.) Information is required as to the carrier or means of transportation by which the merchandise was transported from a foreign country to the first port of unloading in the United States. If the merchandise has been further transported in bond between ports in the United States after having been unladen from the carrier on which it arrived in the United States, the name of the domestic carrier shall not be substituted, and the information furnished shall reflect the name of the carrier or means of transportation by which the merchandise arrived in the first U.S. port of unlading.

(2) For merchandise arriving in the United States by vessel, the name of the importing vessel is required. The importing vessel is the vessel which transported the merchandise from the foreign port of lading to the first U.S. port of unlading.

(3) For merchandise arriving in the United States by air, the name and nationality of the importing airline is required. The importing airline is the airline which carried the merchandise from the foreign port of lading to the first U.S. port of unlading, and not a domestic airline carrying the merchandise after the initial unlading in the United States.

(4) For merchandise arriving in the United States by means of transportation other than vessel or air, the means of transportation from the foreign country is required, in such terms as ''parcel post,'' ''registered mail,'' ''railroad,'' ''trucks,'' ''pipeline,'' etc.

(c) *Foreign port of lading.* (1) (Customs Forms 7501, 7502, 7512 and 7521.) For merchandise arriving in the United States by vessel or air, the name and country of the foreign port at which the merchandise was actually loaded on the vessel or aircraft that carried the merchandise to the United States is required. This information is not required for merchandise entering the U.S. Customs territory from a U.S. Foreign Trade Zone. For shipments originating in either Canada or Mexico by rail, truck, pipeline, or other nonvessel/nonair mode of transportation, supply the name of the province (Canada) or state (Mexico) where the merchandise was first loaded for exportation to the United States.

(2) For merchandise transshipped overseas in the course of shipment to the United States, whether or not covered by a through bill of lading, the information furnished shall reflect only the foreign port at which the merchandise was loaded on the vessel, aircraft, or other carrier which transported it to the first U.S. port of unlading. Neither the foreign port of original lading nor any port of lading other than the last foreign port of lading shall be substituted. When a single Customs form covers merchandise loaded at more than one foreign port, the foreign port of lading shall be indicated separately in the ''Marks and numbers and Country of origin'' column immediately below the Country of origin designation and on the same line as the merchandise laden at each foreign port.

(3) For merchandise entering the U.S. Customs territory from a U.S. Foreign Trade Zone, the number of the Foreign Trade Zone, preceded by the letters ''FTZ'' shall be shown in this space.

(d) *U.S. port of unlading.* (Not required for merchandise entering U.S. Customs territory from U.S. Foreign Trade Zones.) (1) (Customs Forms 7501, 7502, 7512, and 7521.) For merchandise arriving in the United States by vessel or air, the U.S. port (as listed in Schedule D) at which the merchandise was unloaded from the importing vessel or aircraft is required, whether or not such port is a Customs port of entry. (For example, if entry is filed at the Port of Los Angeles for merchandise unloaded from the importing vessel at Long Beach, California, the entry should show Long Beach as the port of unlading.)

(2) When merchandise is transported in bond from the U.S. port where unladen from the importing vessel or carrier to another U.S. port or ports to be entered for consumption or warehouse, the port of unlading required to be shown on the consumption or warehouse entry is the port or point where the merchandise was unladen from the importing vessel or carrier before transportation in bond.

(e) *Date of importation.* (All forms.) For merchandise arriving in the United States by vessel, the month, day, and

year on which the importing vessel transporting the merchandise from the foreign country arrived within the limits of the U.S. port at which the merchandise was or is to be unladen is required. The date of importation to be reported for merchandise arriving in the United States other than by vessel is the date on which the merchandise arrives within the limits of the United States.

(f) *Country of origin.* (1) (All forms.) Country of origin shall be reported in the ''marks and numbers and country of origin'' column on entry and withdrawal forms (in the ''marks and numbers'' column on Forms 7512 and 7500), the ''country of origin'' space on the Special Customs Invoice form, and in a conspicuous place on commercial invoices supplied to Customs where the Special Customs Invoice form is not required. On multipage entries, country of origin should be shown on each page.

(2) Country of origin shall be reported in terms of the names designated in Schedule C–I, ''*Classification of Country* and *Territory Designations for U.S. Import Statistics,*'' unless a more specific geographic area is required to be shown for other purposes. The country of origin is defined as the country in which the product was mined, grown or manufactured. Further labor, work or material added to an article in another foreign country or the Virgin Islands of the United States must effect a substantial transformation in order to render such other country the ''country of origin.'' Such substantial transformations include smelting of ores, refining of crude products, and the like. The country of origin is not changed when the merchandise is subjected in another country merely to minor manipulations, such as sorting, grading, and the like. When the merchandise is invoiced in or exported from a country other than that in which it originated, the actual country of origin shall be specified rather than the country of invoice or exportation. The country of origin for imports of scrap and waste is the country in which the merchandise was reduced to scrap or waste. In the case of such commodities as industrial diamonds or antiques, if the origin of the merchandise is not known or cannot be ascertained with reasonable effort, the country from which the merchandise has been shipped shall be shown and shall be indicated as the ''Country of Shipment.''

(3) Except as provided below, the country of origin shown on import entries and withdrawals should be based on information furnished by the foreign supplier on import invoices. The importer should inform his foreign supplier of the requirements and definitions of this section and instruct the foreign supplier to furnish information on the invoice as to country of origin in accordance with the above definition. If an invoice from the foreign supplier is not available at the time of entry, the importer shall enter the correct country of origin according to his best knowledge. In any case where the importer has reliable knowledge that the country of origin shown on the invoice is incorrect, he shall enter on the form the correct country of origin according to his best knowledge, indicating that it is a correction.

(4) When a single Customs form covers merchandise from more than one country of origin, the country of origin shall be indicated separately against each item (or group of items).

(g) *Description of merchandise.* (All forms.) Except on Customs Form 7512 when used as an Immediate Exportation or Transportation and Exportation entry, the description of merchandise shall be in terms of the Tariff Act in accordance with the Tariff Schedules of the United States Annotated for Statistical Reporting (TSUSA) and in sufficient detail to permit the identification of the TSUSA statistical reporting number to which each commodity properly belongs. The name of the commodity and any and all characteristics of the commodity which distinguish it from commodities of the same name covered by other TSUSA statistical reporting numbers shall be clearly and fully stated. For merchandise classified in TSUSA classifications for which the instruction ''specify by name'' is shown in TSUSA the specific name of the commodity or a further identifying description in addition to the description in the more general terms of the commodity classification definition is required. When

Customs Form 7512 is used as an Immediate Exportation or Transportation and Exportation entry importers need only report in terms of the first five digits of TSUSA (i.e., in terms of TSUS).

(h) *Gross weight in pounds.* (Customs Forms 7501, 7502, 7512, and 7521, for merchandise transported to the United States by vessel or air only.) Gross shipping weight in pounds shall be reported in column (2a) immediately below the description of merchandise (in ''Gross Weight in Pounds'' column on Form 7512 on the same horizontal line with value). Separate gross weight information is required for the merchandise covered by each reporting number, but if gross weight is not available for each reporting number included in one or more packages, approximate shipping weight for each item shall be estimated and reported. The total of these estimated weights should equal the actual gross shipping weight of the entire package or packages. However, for containerized cargo carried in lift vans, cargo vans, or similar substantial outer containers, the weight of such containers should not be included in the gross shipping weight of the merchandise covered by each reporting number.

(i) *Net quantity.* (All forms except 7535.) When a unit of quantity is specified in TSUSA for the reporting number under which the item is reported, net quantity shall be reported in the specified unit, and (except where the unit is ''No.'' (number)) the unit in which reported shall also be shown on the entry following the net quantity figure. In cases where two units of quantity are shown for the commodity in TSUSA, net quantity shall be reported on the import entry in each of the specified units with the unit indicated in each case. The quantity in terms of the unit marked with a superior ''v'' in TSUSA should be shown on the entry on the same horizontal line with the value. The quantity in terms of any other units specified in TSUSA should be shown below the first quantity and should be enclosed in parentheses. If no unit of quantity is specified in TSUSA for the reporting number under which the item is reported, net quantity is not required to be reported on the import entry, and an ''X'' shall be entered in the ''net quantity'' column. Where the unit of quantity specified in TSUSA is ''tons,'' long tons of 2,240 pounds shall be reported unless short tons of 2,000 pounds are specified in TSUSA. Quantities shall be shown in whole units unless fractions of units are required for Customs purposes.

(j) *Value.* (All forms.) Except on Customs Form 7512 when used as an Immediate Exportation or Transportation and Exportation entry, the dollar value shall be reported on the forms in accordance with the definitions set forth in the Tariff Schedules of the United States Annotated (TSUSA) and sections 402 and 402a of the Tariff Act of 1930, as amended. Moreover, the value shall be reported in accordance with the format prescribed in the U.S. Customs Regulations. (On Customs Form 7512 when used as an Immediate Exportation entry, only the Customs value in accordance with sections 402 and 402a of the Tariff Act of 1930, as amended, need be reported.)

(k) *TSUSA reporting number.* (All forms.) Except on Customs Form 7512 when used as an in-transit entry, the reporting number according to the current edition of the Tariff Schedules of the United States Annotated shall be shown in the column provided on the form. The reporting number assigned shall reflect the correct TSUSA classification of the merchandise and be consistent with the rate of duty applicable to the commodity. Where correct reporting as indicated in TSUSA requires the use of more than one TSUSA commodity number, all required reporting numbers will be shown for an item on the Customs form. On Customs Form 7512 when used as an Immediate Exportation or Transportation and Exportation entry, the reporting number, in terms of the first five digits of TSUSA (TSUS), is required to be shown in the column provided on the form for ''Description and Quantity of Merchandise.'' This code should appear to the right of that column, on the same line as the reported gross weight and value.

[41 FR 9134, Mar. 3, 1976, as amended at 42 FR 59839, Nov. 22, 1977; 47 FR 29829, July 9, 1982]

Subpart F—Special Provisions for Particular Types of Import Transactions

§ 30.80 Imports from Canada.

(a) When certain softwood lumber products described under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 4407.1000, 4409.1010, 4409.1090, and 4409.1020 are imported from Canada, import entry records are required to show a valid Canadian Province of Manufacture Code. The Canadian Province of Manufacture is determined on a first mill basis (the point at which the item was first manufactured into a covered lumber product). For purposes of determination, Province of Manufacture is the first province where the subject merchandise underwent a change in tariff classification to the tariff classes cited in this paragraph (a). The Province of Manufacture Code should replace the Country of Origin code on the CF 7501, Entry Summary form. For electronic Automated Broker Interface (ABI) entry summaries, the Canadian Province Code should be transmitted in positions 6–7 of the A40 records. These requirements apply only for imports of certain softwood lumber products for which the Country of Origin is Canada.

(b) All other imports from Canada, including certain softwood lumber products not covered in paragraph (a) of this section, will require the two-letter designation of the Canadian Province of Origin to be reported on U.S. entry summary records. This information is required only for United States imports that under applicable Customs rules of origin are determined to originate in Canada. For nonmanufactured goods determined to be of Canadian origin, the Province of Origin is defined as the Province where the exported goods were originally grown, mined, or otherwise produced. For goods of Canadian origin that are manufactured or assembled in Canada, with the exception of the certain softwood lumber products described in paragraph (a) of this section, the Province of Origin is that in which the final manufacture or assembly is performed prior to exporting that good to the United States. In cases where the province in which the merchandise was manufactured or assembled or grown, mined, or otherwise produced is unknown, the province in which the Canadian vendor is located can be reported. For those reporting on paper forms the Province of Origin code replaces the country of origin code on the CF 7501, Entry Summary form.

(c) All electronic Automated Broker Interface (ABI) entry summaries for imports originating in Canada also require the new Canadian Province of Origin code to be transmitted for each entry summary line item in the A40 record positions 6–7.

(d) The Province of Origin code replaces the Country of Origin code only for imports that have been determined, under applicable Customs rules, to originate in Canada.

Valid Canadian Province/Territory Codes are:

XA—Alberta
XB—New Brunswick
XC—British Columbia
XM—Manitoba
XN—Nova Scotia
XO—Ontario
XP—Prince Edward Island
XQ—Quebec
XS—Saskatchewan
XT—Northwest Territories
XW—Newfoundland
XY—Yukon Territory

[61 FR 60532, Nov. 29, 1996; 61 FR 65319, Dec. 12, 1996]

§ 30.81 Imports of merchandise into Guam.

(a) Carriers of merchandise to Guam shall not be permitted to unload cargo in Guam until the master or other person in charge of the carrier shall deliver to the Government of Guam at the place of unloading a manifest, cargo list, freight list or equivalent document showing a detailed account of merchandise destined for Guam on board such carrier, with the numbers and description of the packages according to their usual name or designation.

(b) For each shipment imported into Guam except as listed in paragraph (d) of this section, the importer in Guam shall furnish to the Government of Guam at the port of entry of the merchandise at the time of or prior to taking possession of such merchandise, the

commercial invoice covering the shipment attached to a copy of the bill of lading or air waybill signed by the carrier. (Where the shipment is one for which no bill of lading (or air waybill) is utilized only a copy of the commercial invoice need be furnished.) In individual cases, where warranted in the opinion of the Government of Guam, the Government of Guam may release merchandise to the consignee prior to receipt of the commercial invoice and/or bill of lading or air waybill in the case of perishable articles or other merchandise, the immediate delivery of which is necessary.

(c) Information concerning individual transactions furnished to the Government of Guam pursuant to these regulations may not be disclosed by those having possession of or access to any copies of such information for official purposes, to anyone other than the exporter or importer except as specifically directed by the Bureau of the Census.

(d) The following kinds of shipments are not to be included in the statistics on shipments from the United States to Guam and the documentation prescribed in paragraphs (a) and (b) of this section shall not be required for statistical purposes:

(1) Shipments to the U.S. Armed Forces;

(2) Shipments of office furniture, office equipment, and office supplies, to and for the exclusive use of U.S. Government offices;

(3) Baggage and personal effects, accompanied or unaccompanied, of persons leaving the U.S., and tools of trade, as described in §30.56(a) and (b).

§30.82 Identification of U.S. merchandise returned for repair and reexport.

Import entries covering U.S. merchandise imported temporarily for repair or alteration and reexport are required to show the following statement: ''Imported for Repair and Reexport.''

§30.83 Statistical copy of mail and informal entries.

A legible copy of all mail and informal entries is required for statistical purposes. In addition to the information required to be shown for customs purposes, the value is also required to be shown for all merchandise including that not subject to duty.

Subpart G—General Administrative Provisions

§30.90 Confidential information, import entries and withdrawals.

The contents of the statistical copies of import entries and withdrawals on file with the Bureau of the Census are treated as confidential and will not be released without authorization by the U.S. Customs Service, in accordance with the policy set forth in 19 CFR 103.4 (Customs Regulations) relating to the copies on file in Customs offices.

§30.91 Confidential information, Shipper's Export Declarations.

(a) *Confidential status.* The Shipper's Export Declaration is an official Department of Commerce form, prescribed jointly by the Bureau of the Census and the International Trade Administration. Information supplied thereon is confidential, for use solely for official purposes authorized by the Secretary of Commerce. Use for unauthorized purposes is not permitted. Information on Shipper's Export Declarations may not be disclosed to anyone except the exporter or his agent by those having possession of or access to any copy for official purposes, except as provided in paragraph (e) of this section.

(b) *Copying of information to manifests not permitted.* Since certain types of information from the outward manifests of ocean carriers can be made public under the provisions of the Customs Regulations, carriers are not permitted to copy information to manifests (or to bills of lading used in lieu of a listing of cargo on a manifest) from Shipper's Export Declarations in their possession for official purposes, except for (1) the bill of lading number on the declaration, (2) information on the declaration which is identical with bills of lading or other sources of information available to the carrier, and (3) items of information which are required by Export Administration Regulations to be identical or consistent on both documents.

(c) *Supplying of copies by exporters for unofficial purposes not permitted.* The regulations in this part spell out precise definitions to be followed in reporting information on Shipper's Export Declarations. Strict adherence to these definitions is necessary if the official purposes for which the forms are required are to be effectively accomplished. Because of the possibility that for other purposes different definitions would be appropriate, the supplying by exporters of any copies (or of the information from copies) for any unofficial purpose is considered detrimental to official objectives and is not permitted.

(d) *Limitations on issuance and reproduction of copies.* Consistent with the policy stated in paragraph (c) of this section, and with the confidential status of the document generally, the following limitations are placed upon the issuance of copies to exporters or their agents:

(1) A copy of a Shipper's Export Declaration may be supplied to exporters or their agents only when such a copy is needed by the exporter to comply with: (i) Official requirements for presentation of a copy to the exporting carrier as authorization for export, (ii) export control requirements, or (iii) U.S. Department of Agriculture requirements for proof of export in connection with subsidy payments. Copies issued to exporters or their agents under paragraph (d)(1) (ii) or (iii) of this section will be stamped as follows by the Customs Director:

Certified pursuant to the Export Administration Regulations or to fulfill the requirements of a Federal Agency and not for any other purpose. May not be reproduced in any form.

(2) Use of copies of the Shipper's Export Declaration in connection with claims for exemption from internal revenue taxes or state taxes is not permitted.

(e) *Determination by the Secretary of Commerce.* When the Secretary of Commerce or delegate determines that the withholding of information provided by an individual Shipper's Export Declaration is contrary to the national interest, the Secretary or delegate may make such information available, taking such safeguards and precautions to limit dissemination as deemed appropriate under the circumstances. In recommendations regarding such actions, the Bureau of the Census will, in general, consider that it is not contrary to the national interest to withhold information on Shipper's Export Declarations from private individuals or businesses (except the exporter or the agent of the exporter) or from state or local government agencies or officials, regardless of the purposes for which the information may be requested. In recommendations regarding any other requests for access to official copies, a judgment in the light of circumstances will be made as to whether it is contrary to the national interest to apply the exemption, keeping in view that the maintenance of confidentiality has in itself an important element of national interest.

(13 U.S.C.302; and 5 U.S.C. 301; Reorg. Plan No. 5 of 1950, Department of Commerce Organization Order No. 35–2A, August 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 47 FR 7213, Feb. 18, 1982; 48 FR 52701, Nov. 22, 1983]

§ 30.92 Statistical classification schedules.

The following statistical classification schedules referred to in the regulations in this part are hereby incorporated by reference. Information as to where copies may be obtained is indicated. Copies are available for public inspection at the offices of local Customs Directors and Department of Commerce District Offices.

TSUSA—Tariff Schedules of the United States Annotated for Statistical Reporting, as currently revised, shows the 7-digit statistical reporting number to be used in preparing import entries and withdrawal forms. TSUSA may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, local Customs Directors, or Department of Commerce District Offices located in principal cities. Purchase price includes the basic schedule plus revisions as currently issued for an indefinite period.

Schedule B—Statistical Classification of Domestic and Foreign Commodities Exported from the United States, as currently revised, shows the detailed commodity classification requirements and 7-digit statistical reporting numbers to be used in preparing Shipper's Export Declarations, as required by these regulations. Schedule B may be purchased from the Superintendent of Documents, U.S.

Government Printing Office, Washington, D.C. 20402, local Customs Directors, or Department of Commerce District Offices located in principal cities. Purchase price includes the basic schedules and supplements issued irregularly, covering revision in the schedule for an indefinite period.

Schedule C–E—Classification of Country and Territory Designations for U.S. Export Statistics. Free from the Bureau of the Census, Washington, D.C. 20233.

Schedule C–I—Classification of Country and Territory Designations for U.S. Import Statistics. Free from the Bureau of the Census, Washington, D.C. 20233.

Schedule D—Classification of Customs Districts and Ports. Free from the Bureau of the Census, Washington, D.C. 20233.

(13 U.S.C. 302; 5 U.S.C. 301; Reorganization Plan No. 5 of 1950; Department of Commerce Organization Order No. 35–2A, Aug. 4, 1975, 40 FR 42765)

[41 FR 9134, Mar. 3, 1976, as amended at 42 FR 59840, Nov. 22, 1977; 43 FR 56031, Nov. 30, 1978; 44 FR 1971, Jan. 9, 1979]

§ 30.93 Emergency exceptions.

In individual cases of emergency, where strict enforcement of the regulations in this part would create undue hardship, the Foreign Trade Division of the Bureau of the Census, with the concurrence of the Office of Export Administration in cases where export control requirements are also involved, may authorize such postponements of or exceptions to the requirements of the regulation in this part as are warranted by the circumstances and not inconsistent with the aims of this chapter.

§ 30.94 Instructions to Customs.

Instructions of a continuing nature to Customs with respect to the forwarding of statistical copies of forms and the preparation of special statistical reports not involving requirements upon the public will not be included in the regulations in this part, but will, instead be transmitted to Customs through appropriate administrative channels.

§ 30.95 Penalties for violations.

Any person who violates any provisions of this part, except for violations of the provisions relating to delayed filing of documents under bond as provided by § 30.24, shall be liable to the United States in civil penalty not exceeding $1,000 for each violation, as authorized by section 305 of Chapter 9 of Title 13 of the United States Code.

§ 30.99 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

(a) *Purpose.* This subpart will comply with the requirements of section 3507(f) of the Paperwork Reduction Act (PRA) which requires that agencies display a current control number assigned by the Director of OMB for each agency information collection requirement.

(b) *Display.*

15 CFR section where identified and described	Current OMB control no.
30.1 through 30.7	0607–0001, –0018, –0150, –0152
30.8	0607–0001
30.9 through 30.11	0607–0001, –0018, –0152
30.12 and 30.15	0607–0001, –0018, –0152
30.16	0607–0001, –0018, –0150, –0152
30.20 through 30.24	0607–0001, –0018, –0150, –0152
30.30 through 30.31	0607–0018, –0150, –0152
30.33 through 30.35 and 30.37.	0607–0001, –0018, –0150, –0152
30.39	0607–0018, –0150, –0152
30.40, 30.41, and 30.50 through 30.53.	0607–0001, –0018, –0150, –0152
30.54	0607–0018
30.55 through 30.57	0607–0001, –0018, –0150, –0152
30.82	0607–0018, –0152
30.91 through 30.95	0607–0001, –0018, –0150, –0152

[48 FR 56744, Dec. 23, 1983]

PART 40—TRAINING OF FOREIGN PARTICIPANTS IN CENSUS PROCEDURES AND GENERAL STATISTICS

Sec.

AUTHORITY: 5 U.S.C. 301; 22 U.S.C. 1456; 31 U.S.C. 686. Memorandum of Agreement between the Department of Commerce and the Foreign Operations Administration Concerning Foreign Technical Assistance Work, signed June 10, 1954.

SOURCE: 28 FR 119, Jan. 4, 1963, unless otherwise noted.

§ 40.1 Type of grant.

Training grants will be awarded by the Agency for International Development (AID), in its capacity as the bilateral technical assistance agency for the United States Government, to foreign participants for training, observation, and research in the fields of censuses and statistics at the Bureau of the Census. In compliance with the needs of the participants and consistent with resources of the Bureau, training programs will be developed along the lines of a combined interne-training and/or training-in research types, and may include any or all of the following:

(a) Conference courses designed to provide the trainee with adequate background information on (1) organization and administration of the United States Bureau of the Census, (2) subject-matter areas for which the Bureau of the Census collects and compiles statistical information, (3) nature and scope of the major statistical programs maintained by other federal government agencies, (4) techniques and scope of the periodic censuses and statistical surveys, and statistical compilations undertaken by the Bureau of the Census, and (5) relation of censuses to other statistical data collected and analyzed by U.S. agencies.

(b) Seminars laboratory exercises and observation of work in the Census Bureau and other agencies with specific applicability to the participant such as (1) development of census and survey questionnaires, (2) methods of field and mail enumeration, (3) procedures for editing and coding statistical forms, (4) use of office machines, electromechanical tabulation equipment, and automatic data processing systems for mass processing of statistical data, (5) definitions and scope of the subject matters involved in the censuses and statistical programs of the Bureau of the Census, (6) classification of industrial and business establishments, (7) classification of imports and exports, (8) techniques of making intercensal estimates of population, (9) sampling techniques and quality control procedures, (10) analyses and publication of data, and development of certain indexes; and (11) other topics, particularly in the development of new statistical programs and techniques.

(c) Formal courses at a college or university to supplement the seminars, conference-courses, and individual statistical projects developed, presented, or assigned by the Bureau; or enrolled on a full-time basis in a college or university to obtain the appropriate academic background for further work in the field of statistics in accordance with needs of participants and/or the program requirements of their countries.

(d) Observation trips to various academic institutions with recognized statistical activities, to private marketing and research agencies, to regional field offices of the Bureau, to the government statistical agencies of Canada, and to such activities that will supplement or illustrate the application and end use of statistical data.

(e) Case study workshops on selected census and statistical activities presented at the Bureau, in other locations in the United States, or outside the continental limits of the United States.

(f) Such field training, special research, or university program as appears advisable to the Director of the Bureau of the Census in accordance with the technical needs of the participants.

§ 40.2 Qualifications.

(a) To be eligible for a training grant at the Bureau of the Census the applicant must be:

(1) A bona-fide citizen of a country with whom the United States has proper diplomatic arrangements for such training programs.

(2) Able to speak, read, write, and understand the English language.

(3) Sponsored by his government either directly with the United States or through a public international agency.

(4) Physically able to undertake the activities incident to the course of training and free from communicable diseases.

(b) [Reserved]

§ 40.3 Cooperation with bilateral technical assistance programs of the United States.

In compliance with the provisions contained in the Memorandum of Agreement executed between the Department of Commerce and the Foreign Operations Administration (now AID) on June 10, 1954, the Bureau of the Census is authorized within its areas of competence and available resources to continue its training of foreign nationals under the general guidance of the Department of Commerce and in cooperation with the bilateral technical assistance programs of the United States Government.

§ 40.4 Administrative provisions on selection of participants and funding of costs.

(a) Within the framework of the aforementioned Memorandum of Agreement, the Bureau of the Census will arrange at the request and expense of the Agency for International Development, a program for technical training of foreign participants in censuses and statistics. The Bureau of the Census will be furnished biographic materials, information about the training objecttives including, where appropriate, each participant's education and experience, type of training desired, present and future positions with descriptions of duties, and the terms of the training project for each participant or group as far in advance of his arrival in the United States as possible.

(b) The Bureau reserves the right to accept, based on biographical information to be furnished in advance, only those participants whom it finds qualified to make satisfactory use of its training facilities and resources. The Bureau would prefer to develop programs for foreign participants with substantive experience in the statistical activities of their home country.

(c) Arrangements for security clearances, insurance, orientation, international travel, housing, and other administrative responsibilities will be the responsibility of AID under the provisions of the Memorandum of Agreement (Reference: Appendix II, Training of Foreign Nationals).

§ 40.5 Other cooperative arrangements.

The Bureau of the Census also undertakes the training of foreign nationals proposed through the Department of State under the International Exchange Service (IES) or under the sponsorship of public international agencies.

PART 50—SPECIAL SERVICES AND STUDIES BY THE BUREAU OF THE CENSUS

Sec.

AUTHORITY: Sec. 3, 49 Stat. 293, as amended; 15 U.S.C. 192a. Interprets or applies sec. 1, 40 Stat. 1256, as amended, sec. 1, 49 Stat. 292, sec. 8, 60 Stat. 1013, as amended, 15 U.S.C. 192, 189a, 13 U.S.C. 8.

§ 50.1 General.

(a) Fee structure for age search and citizenship service, special population censuses, and for foreign trade and shipping statistics.

(b) In accordance with the provisions of the acts authorizing the Department of Commerce to make special statistical surveys and studies, and to perform other specified services upon the payment of the cost thereof, the following fee structure is hereby established. No transcript of any record will be furnished under authority of these acts which would violate existing or future acts requiring that information furnished be held confidential.

(c) Requests for age search and citizenship service should be addressed to the Personal Census Search Unit, Data Preparation Division, Bureau of the Census, P.O. Box 1545, Jeffersonville, Indiana 47131. Application forms may be obtained at Department of Commerce field offices or Social Security offices or by writing to the Jeffersonville, Indiana office.

(d) If a search is unsuccessful and additional information for a further

search is requested by the Bureau, such information must be received within 120 days of the request or the case will be considered closed. Additional information received after 120 days must be accompanied by a new fee and will be considered as a new request.

(15 U.S.C. 1526 and 13 U.S.C. 8)

[36 FR 905, Jan. 20, 1971, as amended at 49 FR 3980, Feb. 1, 1984; 56 FR 35815, July 29, 1991]

§50.5 Fee structure for age search and citizenship information.

Type of service	Fee
Searches of one census for one person and one transcript	$40.00
Each additional copy of census transcript	2.00
Each full schedule requested	10.00

NOTE.—The $10.00 for each full schedule requested is in addition to the fee increase to $40.00

[58 FR 4078, Jan. 13, 1993]

§50.10 Fee structure for special population censuses.

The Bureau of the Census is authorized to conduct special population censuses at the request of and at the expense of the community concerned. To obtain a special population census, an authorized official of the community should write a letter to the Associate Director for Demographic Fields, Bureau of the Census, Washington, D.C. 20233, requesting detailed information and stating the approximate present population. The Associate Director will reply giving an estimate of the cost and other pertinent information. Title 13, United State Code, section 196, Special Censuses, requires payment to the Bureau of the actual or estimated cost of each such special census.

[47 FR 18, Jan. 4, 1982]

§50.30 Fee structure for foreign trade and shipping statistics.

(a) The Bureau of the Census is willing to furnish on a cost basis foreign trade and shipping statistics provided there is no serious interruption of the Bureau's regular work program.

(b) In instances where information requested is not shown separately or not summarized in the form desired, it is necessary to conduct a prelimary investigation at the requestor's expense to determine whether the information can be compiled from the basic records and what the total cost will be. The preliminary investigation normally costs $250 but may be more depending on the circumstances. The total cost of the final report generally ranges from $500 to several thousand dollars for data covering a 12-month period.

(c) Upon receipt of a request, information will be furnished as to whether the statistics are available and if so, the cost; or that a preliminary investigation must be conducted. When an investigation is completed, information will be furnished as to the cost of preparing the material, or as to the reason if the statistics cannot be compiled from our basic records.

(15 U.S.C. 1526 and 13 U.S.C. 8)

[28 FR 120, Jan. 4, 1963, as amended at 49 FR 3980, Feb. 1, 1984]

§50.40 Fee structure for statistics for city blocks in the 1980 Census of Population and Housing.

(a) As part of the regular program of the 1980 census, the Census Bureau will publish printed reports containing certain summary population and housing statistics for each city block, drawn from the subjects which are being covered on a 100-percent basis. For these subjects, a substantial amount of additional data by block will be available on computer tape.

(b) The 1980 block data under the regular program will be prepared for:

(1) Each urbanized area in the United States. An urbanized area is delineated by the Census Bureau in each standard metropolitan statistical area and generally consists of a city or group of contiguous cities with a 1970 population of 50,000 or more, together with adjacent densely populated land (i.e., land having a population density of at least 1,000 persons per square mile).

(2) And, outside urbanized areas, for each incorporated place (such as a city or village) that was reported as having 10,000 or more inhabitants in:

(i) The 1970 census, or

(ii) The 1973, 1975, or 1976 official population estimates published by the Bureau, or

(iii) A special census conducted by the Bureau on or before December 31, 1977.

(c) Outside the above-mentioned urbanized areas and places, State and local government authorities will be able to contract with the Bureau of the Census to produce block data for their areas. In undertaking this contract, the requesting authority will be required to pay a fee, supply certain maps, and meet certain time deadlines as follows:

(1) *Fee:* (i) Population size:

	Fee per area
Under 2,500	$500
2,500 to 4,999	600
5,000 to 9,999	700

(ii) The final fee will be based upon the 1980 census population counts. A refund or additional charge will be made if the contracting area is in a different population size group as a result of the census.

(iii) The cost for an area with a population of 10,000 or more will be determined on an individual basis.

(iv) Multiple area contracts may be negotiated at a savings.

(v) The fee is based on estimated 1980 costs. If the 1980 cost exceeds the estimated cost, an additional fee may be requested from the contracting area. If actual costs are less than the estimated cost, a refund may be made.

(vi) Any incorporated place which contracts for block statistics and which reaches a population of 10,000 or more in the 1980 census will have the fee completely refunded, as the place will then be considered to be part of the regular block statistics program.

(vii) If the area submits maps which are not adequate for the Bureau's purposes (see Maps, below) and therefore have to be redrafted by the Bureau, a surcharge of $300 per map sheet requiring revision will be applied to the fee for the particular area.

(2) *Maps:* (i) In order for the Bureau to provide data on a block-by-block basis, it must have a map which clearly delineates each block. The contracting government authority must supply such maps. A copy of the specifications for preparing the block maps will be provided upon request and, in any event, will accompany the copy of the contract which is sent to the government authority for signature.

(ii) The maps must be furnished to the Census Bureau within 30 calendar days after the government authority signs the contract.

(iii) The Bureau will review the maps and, if revision is necessary, return them within 30 calendar days to the government authority.

(iv) Within 30 calendar days thereafter, the revised maps must be transmitted to the Bureau and, if they are still inadequate and must therefore be redrafted by the Bureau, the above-mentioned surcharge of $300 per map sheet requiring revision will be imposed.

(3) *Timing:* (i) The contract must be signed, and a downpayment of $250 per area made, by April 1, 1978. A check or money order should be made payable to ''Commerce—Census.''

(ii) If an area decides to withdraw after signing a contract and making a downpayment, the cost of work performed to date will be deducted from the refund.

(iii) The balance of the fee must be mailed to the Bureau by January 1, 1980.

(d) In consideration of the fees paid and maps supplied, the Bureau will:

(1) Identify the individual blocks in its records and tabulations.

(2) Make available the block data for the particular area in the same manner as for areas in the regular block statistics program (i.e., both in terms of printed reports and computer summary tapes). Two copies of the printed report (including the printed maps) which contain the block statistics for the particular area will be furnished to the contracting government authority.

(e) Requests for participation in the contract block statistics program or for further information should be addressed to the Director, Bureau of the Census, Washington, DC 20233.

[43 FR 3903, Jan. 30, 1978; 43 FR 59835, Dec. 22, 1978]

PART 60—PUBLIC INFORMATION

AUTHORITY: 5 U.S.C. 301, 552, 553, Reorganization Plan No. 5 of 1950; 31 U.S.C. 3717.

§ 60.1 Public information.

The rules and procedures regarding public access to the records of the Bureau of the Census are found at 15 CFR part 4.

[57 FR 40841, Sept. 8, 1992]

PART 70—CUTOFF DATES FOR RECOGNITION OF BOUNDARY CHANGES FOR THE CENSUS 2000

Sec.

AUTHORITY: 13 U.S.C. 4 and Department of Commerce Organization Order 35–2A (40 FR 42765).

SOURCE: 51 FR 24653, July 8, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 70 appear at 63 FR 10303, Mar. 3, 1998.

§ 70.1 Cutoff dates and effect on enumeration and data tabulation.

For the tabulation and publication of data from the Census 2000 of Population and Housing, the Bureau of the Census will recognize only those boundaries legally in effect on January 1, 2000 that have been reported officially to the Bureau of the Census no later than March 1, 2000. The Bureau of the Census enumerates respondents on the date of the decennial census as residing within the legal limits of municipalities, county subdivisions, counties, States, and equivalent areas as those limits exist on January 1, 2000.

§ 70.2 "Municipality" and "county subdivision" defined for census purposes.

For the purposes of this part, the Bureau of the Census defines ''municipalities'' and ''county subdivisions'' to include the areas identified as incorporated places (such as cities and villages) and minor civil divisions (such as townships and magisterial districts). A more complete description appears on pages A–6 and A–11 of 1990 Census of Population, Volume 1, General Population Characteristics, 1990 CP–1–1, Appendix A.

[51 FR 24653, July 8, 1986, as amended at 63 FR 10303, Mar. 3, 1998]

§ 70.3 Effect of boundary changes occurring or reported after the cutoff dates.

The Bureau of the Census will not recognize changes in boundaries that become effective after January 1, 2000 in taking the 2000 Decennial Census; the Bureau of the Census will enumerate the residents of any area that are transferred to another jurisdiction after that date and report them for the Census 2000 as residents of the area in which they resided on January 1, 2000. The Bureau of the Census will not recognize in the data tabulations prepared for the 2000 census changes occurring on or before January 1, 2000, but not submitted officially to the Bureau of the Census until after March 1, 2000 except as necessary to conduct decennial census operations.

PART 80—FURNISHING PERSONAL CENSUS DATA FROM CENSUS OF POPULATION SCHEDULES

Sec.

AUTHORITY: Sec. 1, Pub. L. 83–1158, 68 Stat. 1013 (13 U.S.C. 8).

§ 80.1 General requirements.

(a) Data from records of decennial census of population questionnaires pertaining to an individual will be released only in accordance with these rules.

(b) Census information contains only the responses recorded by the Census enumerator; no changes of any of these entries have been or can be made.

(c) Requests for information from decennial census of population records (herein ''Census information'') should be made on Form BC–600, which is available from offices of the Bureau of

the Census at Suitland, Maryland 20233 and Pittsburg, Kansas 66762, all county courthouses, Social Security field offices, and Immigration and Naturalization Service offices. A letter request—without Form BC–600—will be accepted only if it contains the information necessary to complete a Form BC–600. No application will be processed without payment of the required fee as set forth in 15 CFR 50.5.

(d) The Bureau may require verification of the identity of the applicant requesting Census information and it may require the applicant to submit the following notarized statement:

I, _____ (Printed name), do hereby certify that I am the individual to whom the requested record pertains or that I am within the class of persons authorized to act on his behalf in accordance with 15 CFR, Part 80.

(Signature) _____

(Date)_____

In the County of _____

State of _____

On this ____ day of _____, 19__, _____ (Name of individual) who is personally known to me, did appear before me and sign the above certificate.

(Signature) _____

(Date)_____

(S) My commission expires _____

(e) Except as otherwise provided, Census information will be provided only to the individual to whom the record pertains. It will include the names of the subject and the head of the household, the relationship of the subject to the head of the household, and the subject's age and birthplace.

(f) Similar Census information pertaining to other members of a household will be furnished only upon written authorization of the individual whose record is requested, except as provided in § 80.3.

(g) Census information may be provided to others only upon signed request by an individual entitled to receive the information which indicates the person and address to which the information is to be sent.

(Approved by the Office of Management and Budget under control number 0607–0117)

[40 FR 53232, Nov. 17, 1975, as amended at 48 FR 56744, Dec. 23, 1983]

§ 80.2 Rules pertaining to records of the living.

(a) An individual who has attained age 18 may request his or her own Census information.

(b) A parent may request Census information for and in behalf of a child who has not reached age 18. The request must be signed by one of the parents.

(c) A legal guardian may obtain Census information relating to a ward by submitting a certified copy of the order of guardianship appointment.

(Approved by the Office of Management and Budget under control number 0607–0117)

[40 FR 53232, Nov. 17, 1975, as amended at 48 FR 56744, Dec. 23, 1983]

§ 80.3 Rules applicable to deceased persons and estates.

(a) Census information relating to a deceased person may be released only to a parent, child, grandchild, brother, sister, spouse, insurance beneficiary, or the executor or administrator of a deceased person's estate. The request must be signed by a person entitled to receive the information as provided herein, state the relationship of the applicant to the deceased, and include a certified copy of the death certificate or other adequate proof of death. The request of an executor or administrator must be accompanied by a certified copy of the court order of appointment.

(b) Except for a spouse, a person related to the deceased person through marriage, such as an in-law relationship, is not eligible to request Census information on the deceased, whether or not the applicant was a member of the household of the deceased.

(Approved by the Office of Management and Budget under control number 0607–0117)

[40 FR 53232, Nov. 17, 1975, as amended at 48 FR 56744, Dec. 23, 1983]

§ 80.4 Signature of persons unable to sign their name.

A person requesting Census information who is unable to sign his or her name shall make an ''X'' mark where signature is required, and the mark must be witnessed by two persons who know the applicant. They must also sign the application certifying the applicant's identity. In the case of such

persons who are unable to make an ''X'' mark, Census information can be released upon receipt of a physician's sworn statement verifying the disability and the written request of a parent, brother, sister, child or a spouse.

(Approved by the Office of Management and Budget under control number 0607–0117)

[40 FR 53232, Nov. 17, 1975, as amended at 48 FR 56744, Dec. 23, 1983]

§ 80.5 Detrimental use of information.

Section 8 of Title 13, United States Code requires that,

In no case shall information furnished under the authority of this section be used to the detriment of the persons to whom such information relates.

[40 FR 53232, Nov. 17, 1975]

§ 80.6 False statements.

Any false statement or forgery on the application or supporting papers required to obtain Census information is punishable by a fine and/or imprisonment pursuant to section 1001 of Title 18 of the United States Code.

(Approved by the Office of Management and Budget under control number 0607–0117)

[40 FR 53232, Nov. 17, 1975, as amended at 48 FR 56744, Dec. 23, 1983]

PART 90—PROCEDURE FOR CHALLENGING CERTAIN POPULATION AND INCOME ESTIMATES

Sec.

AUTHORITY: 13 U.S.C. 4 and 181.

SOURCE: 44 FR 20647, Apr. 6, 1979, unless otherwise noted.

§ 90.1 Scope and applicability.

These rules prescribe the administrative procedure available to States and units of local government to challenge the current estimates of population or per capita income developed by the Bureau of the Census.

§ 90.2 Policy of the Bureau of the Census.

It is the policy of the Bureau of the Census to provide the most accurate population and per capita income estimates possible given the constraints of time, money, and available statistical techniques. It is also the policy of the Bureau to provide States and units of local government the opportunity to challenge these estimates and to present probative evidence relating to the accuracy of the estimates.

§ 90.3 Definitions.

As used in this part (except where the context clearly indicates otherwise) the following definitions shall apply:

(a) *Bureau* means the Bureau of the Census, Department of Commerce.

(b) *Challenge* means, in accordance with this part, the process of objecting to or calling into question the Bureau's population or per capita income estimates of a State or unit of local government by that State or unit of local government. A demand for adjustment to the General Revenue Sharing Act, Pub. L. 92–512, section 102(b), as amended (31 U.S.C. 1222(b)) does not constitute a challenge within the meaning of this part.

(c) *Director* means Director of the Bureau of the Census, or an individual designated by the Director to perform under this part.

(d) *Estimate* means a statistically derived intercensal population or per capita income figure prepared to update earlier census figures.

(e) *State* includes the District of Columbia.

(f) *Unit of local government* means the government of a county, municipality, township, place, or other minor civil

division, which is a unit of general government below the State.

§ 90.4 General.

This part provides a procedure for a State or unit of local government to challenge the population or per capita income estimates of the Bureau. The Bureau shall receive these challenges and attempt to resolve them informally with the locality. If the challenge is not resolved informally, the challenging State or unit of local government may then, at its option, proceed formally.

§ 90.5 When an informal challenge may be filed.

An informal challenge to the population or per capita income estimates may be filed any time up to 180 days after the release of the estimates by the Bureau of the Census. Publication by the Bureau of the Census and simultaneous publication of a release notification in the FEDERAL REGISTER shall constitute release. A challenge to any estimate may also be filed any time up to 180 days from the date the Census Bureau, on its own initiative, revises that estimate.

If, however, a State or unit of local government has sufficiently meritorious reason for not filing in a timely manner, the Census Bureau has the discretion to accept the challenge.

[50 FR 28768, July 16, 1985]

§ 90.6 Where to file challenge.

A challenge must be prepared in writing by the unit of government and is to be filed with the Chief, Population Division, Bureau of the Census, Room 2011, Federal Building 3, Washington, D.C. 20233.

§ 90.7 Evidence required.

The challenging State or unit of local government shall provide whatever evidence it has relative to the challenge at the time the challenge is filed. The Bureau may request further evidence.

§ 90.8 Review of challenge.

The Chief, Population Division, Bureau of the Census, or the Chief's designee shall review the challenge and the evidence supporting the challenge and shall attempt to resolve the challenge.

§ 90.9 When formal procedure may be invoked.

In the event the Chief, Population Division, is unable to resolve the challenge to the satisfaction of the challenging State or unit of local government, the challenging State or unit of local government shall be informed in writing of the reasons for the outcome and of its right to proceed formally.

§ 90.10 Form of formal challenge and time limit for filing.

The formal challenge shall be in writing and may be mailed or hand delivered to the Director, Bureau of the Census, Washington, D.C. 20233. The formal challenge shall include a list indicating the material submitted to the Chief, Population Division, during the informal stage, and shall include any additional relevant material it chooses to submit. The formal challenge shall be filed within 30 days of the date the State or unit of local government receives notification by certified mail (return receipt requested) of its right to proceed formally. If, however, a State or unit of local government has a sufficiently meritorious reason for not filing in a timely manner, the Bureau has the discretion to accept the formal challenge.

§ 90.11 Appointment of hearing officer.

Upon receipt of a formal challenge filed in accordance with this part, the Director will appoint a hearing officer to receive written and oral evidence.

§ 90.12 Qualifications of hearing officer.

The hearing officer, a person not involved in the preparation of the estimates being challenged, shall be appointed by the Director from a roster of employees of the Bureau of the Census who have been approved in advance by the Assistant Secretary for Administration, Department of Commerce.

§ 90.13 Offer of hearing.

The hearing officer shall receive the formal challenge and shall notify the State or unit of local government in writing of (a) its right to a hearing

prior to the development of a recommended decision for the consideration of the Director; and (b) its right to the development of a recommended decision for the consideration of the Director without a hearing. If the State or unit of local government requests that a hearing be conducted, the hearing officer shall establish the date, time, and meeting place for the hearing, in accordance with §19.14a.

§90.14 Hearing.

(a) The hearing shall be conducted by the same hearing officer who collected the documentary evidence, if possible, and shall be held at Bureau of the Census headquarters in Suitland, Md., unless the hearing officer determines that the hearing should be held elsewhere.

(b) The hearing shall be conducted in a manner so as to bring out the pertinent facts relating to the challenge.

(c) The rule of evidence will not be strictly enforced but irrelevant and unduly repetitious testimony shall be excluded.

(d) Cross-examination of all witnesses is permitted and all testimony shall be received under oath or affirmation.

(e) The hearing officer shall have the authority to: (1) Administer oaths or affirmations, (2) rule on the admissibility of evidence, (3) limit the number of witnesses, (4) exclude any person from the hearing room for contumacious conduct or misbehavior that obstructs the hearing, (5) perform other such acts as are necessary or appropriate to the efficient conduct of any proceeding, and (6) make initial findings, analyses, and recommendations.

(f) The hearing shall be recorded but no written record will be prepared unless the Bureau so orders or unless the challenging locality desires one in whole or part and pays the costs of such a written record, or the apportioned costs should the Bureau also desire a written record.

(g) The hearing officer shall prepare findings, analyses, and recommendations and shall transmit them along with all documentary evidence received and the tape or written record (if any) of the hearing to the Director.

[44 FR 20647, Apr. 6, 1979, as amended at 50 FR 18990, May 6, 1985]

§90.15 Decision by Director.

Upon receiving the material specified in §90.14(g), the Director shall (a) review the findings and recommendations of the hearing officer, and (b) prepare and transmit a letter to the challenging State or unit of local government stating the decision and the reasons therefor. A copy of the hearing officer's findings, analyses, and recommendations shall also be transmitted to the challenging State or unit of local government, and is otherwise publicly available. This decision is final for the Department of Commerce.

§90.16 Notification of adjustment.

In the event that the Director finds that the population or per capita income estimate should be adjusted, the Bureau shall promptly inform the appropriate governmental agencies of the revision.

§90.17 Timing for hearing and decision.

A maximum period of 120 days, unless additional time is required for sufficiently meritorious reason, shall be provided beyond the closing date for the filing of informal challenges to allow for (a) resolution of informal challenges, (b) appointment of the hearing officer, and (c) the completion of formal hearings. A maximum of 30 additional days shall be allowed for deliberations by the hearing officer and staff. A maximum of an additional 30 days shall also be provided beyond this during which the Census Bureau Director must rule on all cases. Neither the timing nor the general provisions contained in these regulations shall affect the rights of communities to a review through the data improvement program of the Office of Revenue Sharing under the provisions of Pub. L. 92–512, section 102(b), as amended (31 U.S.C. 1222(b)). Localities challenging only through the Office of Revenue Sharing may not have access to a formal hearing as provided in these regulations.

§90.18 Representation.

A challenging unit of government may be represented by its chief executive officer or by counsel, or other duly

authorized representative as designated by the chief executive officer in writing to the Bureau.

PART 100—SEAL

Sec.
100.1 Authority.
100.2 Description.
100.3 Custody.

AUTHORITY: R.S. 161, as amended, sec. 3, 68 Stat. 1012, as amended (5 U.S.C. 301, 13 U.S.C. 3).

SOURCE: 25 FR 2163, Mar. 16, 1960, unless otherwise noted. Redesignated at 50 FR 23947, June 7, 1985.

§ 100.1 Authority.

Pursuant to section 3 of Title 13, United States Code, the Bureau of the Census official seal and design thereof, which accompanies and is made a part of this document, is hereby approved.

§ 100.2 Description.

Seal: On a shield an open book beneath which is a lamp of knowledge emitting rays above in base two crossed quills. Around the whole a wreath of single leaves, surrounded by an outer band bearing between two stars the words ''U.S. Department of Commerce'' in the upper portion and ''Bureau of the Census'' in the lower portion, the lettering concentric with an inner beaded rim and an outer dentilated rim.

§ 100.3 Custody.

The seal shall remain in the custody of the Director, Bureau of the Census or such officer or employee of the Bureau as he designates and shall be affixed to all certificates and attestations that may be required from the Bureau.

PARTS 101—199

[RESERVED]

CHAPTER II—NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, DEPARTMENT OF COMMERCE

SUBCHAPTER A—MEASUREMENT SERVICES

SUBCHAPTER B—STANDARD REFERENCE MATERIALS

SUBCHAPTER C—TRANSCRIPT SERVICES—[RESERVED]

SUBCHAPTER D—STANDARDS FOR BARRELS

SUBCHAPTER E—FELLOWSHIPS AND RESEARCH ASSOCIATES

SUBCHAPTER F—REGULATIONS GOVERNING TRAFFIC AND CONDUCT

SUBCHAPTER G—INVENTION EVALUATION PROCEDURES [RESERVED]

SUBCHAPTERS H–I [RESERVED]

SUBCHAPTER J—ACCREDITATION AND ASSESSMENT PROGRAMS

SUBCHAPTER A—MEASUREMENT SERVICES

PART 200—POLICIES, SERVICES, PROCEDURES, AND FEES

Sec.

AUTHORITY: Sec. 9, 31 Stat. 1450, as amended; 15 U.S.C. 277. Interprets or applies sec. 7, 31 Stat. 1450; 15 U.S.C. 275a.

SOURCE: 45 FR 55166, Aug. 19, 1980, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 200 appear at 55 FR 38315, Sept. 18, 1990.

§ 200.100 Statutory functions.

(a) The National Institute of Standards & Technology (NIST) has been assigned the following functions (15 U.S.C. 271 *et seq.*):

(1) The custody, maintenance, and development of the national standards of measurement, and the provision of means and methods for making measurements consistent with those standards, including the comparison of standards used in scientific investigations, engineering, manufacturing, commerce, and educational institutions with the standards adopted or recognized by the Government.

(2) The determination of physical constants and properties of materials when such data are of great importance to scientific or manufacturing interests and are not to be obtained with sufficient accuracy elsewhere.

(3) The development of methods for testing materials, mechanisms, and structures, and the testing of materials, supplies, and equipment, including items purchased for use of Government departments and independent establishments.

(4) Cooperation with other governmental agencies and with private organizations in the establishment of standard practices, incorporated in codes and specifications.

(5) Advisory service to Government agencies on scientific and technical problems.

(6) Invention and development of devices to serve special needs of the Government.

(b) The calibration and testing activities of NIST stem from the functions in paragraphs (a) (1) and (3) of this section. NIST provides the central basis within the United States for a complete and consistent system of measurement; coordinates that system, and the measurement systems of other nations; and furnishes essential services leading to accurate and uniform physical measurements throughout this Nation's scientific community, industry, and commerce.

(c) The provision of standard reference materials for sale to the public is assigned to the Office of Standard Reference Materials of the National Measurement Laboratory, NIST. That Office evaluates the requirements of science and industry for carefully characterized reference materials, stimulates efforts of NIST to develop methods for production of needed reference materials and directs their production and distribution. For further information on standard reference materials see Subchapter B, Chapter II, Part 230, of this title.

§ 200.101 Measurement research.

(a) The NIST staff continually reviews the advances in science and the trends in technology, examines the measurement potentialities of newly discovered physical phenomena, and uses these to devise and improve standards, measuring devices, and measurement techniques. As new requirements appear, there are continual shifts of program emphasis to meet the most urgent needs for the measurement of additional quantities, extended ranges, or improved accuracies.

(b) The basic research and development activities of NIST are primarily funded by direct appropriations, and are aimed at meeting broad general needs. NIST may also undertake investigations or developments to meet some specialized physical measurement problem of another Government agency, industrial group, or manufacturing firm, using funds supplied by the requesting organization.

§ 200.102 Types of calibration and test services.

(a) NIST has developed instrumentation and techniques for realizing standards for the seven base units of the International System of Units, as agreed upon by the General Conference of Weights and Measures. Reference standards have been established not only for these seven base units, but also for many derived quantities and their multiples and submultiples. Such reference standards, or equivalent working standards, are used to calibrate laboratory and plant standards for other organizations. Accuracy is maintained by stability checks, by comparison with the standards of other national and international laboratories, and by the exploration of alternative techniques as a means of reducing possible systematic error.

(b) Calibrations for many types of instruments and ranges of physical quantities are described in the NIST Special Publication 250 (SP 250). (See § 200.115 for details relating to the description of service items and listing of fees.)

(c) In recent years NIST has offered to the public new measurement services called measurement assurance programs. These programs are designed for laboratories whose measurement process involves the calibration of other standards. A measurement assurance program is a measurement quality control process. By use of carefully designed redundant measurements and measurements made on NIST transport standards a total uncertainty of the laboratories measurement process can be determined by NIST. The results of these tests are then reported to the customer as uncertainties of the customer's measurements relative to national standards.

(d) Special measurements not listed in SP 250 may be made upon request. These might involve unusual physical quantities, upper or lower extremes of range, higher levels of accuracy, fast response speeds, short durations, broader ranges of associated parameters, or special environmental conditions. Such inquiries should describe clearly the measurement desired. Indication of the scientific or economic basis for the requirements to be satisfied will be helpful in determining future NIST programs. Fees for work accepted will be based upon actual costs incurred.

(e) The principal emphasis of NIST is on those calibrations and other tests requiring such accuracy as can be obtained only by direct comparison with its standards.

(f) Other services which may be obtained include:

(1) Tests of measuring instruments to determine compliance with specifications or claims, when the evaluation is critical in national scientific or technical operations, and when suitable facilities are not available elsewhere; and

(2) Referee tests in important cases when clients are unable to agree upon the method of measurement, the results of tests, or the interpretation of these results, but have agreed in advance in writing to accept and abide by the findings of NIST.

(g) NIST reserves the right to decline any request for services if the work would interfere with other activities deemed by the Director to be of greater importance. In general, measurement services are not provided when available from commercial laboratories.

(h) Suggestions will be offered on measurement techniques and on other sources of assistance on calibration or measurement problems when the equipment and personnel of NIST are unable to undertake the work. The National Conference of Standards Laboratories issues a Directory of Standards Laboratories in the United States which perform calibration work (obtainable from NCSL Secretariat, c/o National Institute of Standards & Technology, Boulder, CO 80303). Those laboratories which perform testing are listed in the

ASTM Directory of Testing Laboratories, Commercial and Institutional. (Directory available from the Amercian Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.) Similar listings appear in buyer's guides for commercial products and in technical journals concerned with physical measurement.

§ 200.103 Consulting and advisory services.

(a) In areas of its special competence, NIST offers consulting and advisory services on various problems related to measurement, e.g., details of design and construction, operational aspects, unusual or extreme conditions, methods of statistical control of the measurement process, automated acquisition of laboratory data, and data reduction and analysis by computer. Brief consultation may be obtained at no charge; the fee for extended effort will be based upon actual costs incurred. The services outlined in this paragraph do not include services in connection with legal proceedings not involving the United States as a named party, nor to testimony or the production of data, information, or records in such legal proceedings which is governed by the policies and procedures set forth in Subchapter H, Chapter II, Part 275, of this title.

(b) To enhance the competence of standards laboratory personnel, NIST conducts at irregular intervals several group seminars on the precision measurement of specific types of physical quantities, offering the opportunity of laboratory observation and informal discussion. A brochure describing the current series of seminars can be obtained by writing the Office of Measurement Services, National Institute of Standards & Technology, Washington, DC 20234.

§ 200.104 Standard reference materials.

Often the performance of a device or structure can be evaluated at the user's laboratory by comparing its response to unknown materials with its response to a stable, homogeneous reference specimen which has been well-characterized with regard to the physical or chemical property being measured. For information regarding carefully characterized materials see Subchapter B, Chapter II, Part 230, of this title. The Office of Standard Reference Materials in the NIST National Measurement Laboratory administers a program to provide many types of well-characterized materials that are needed to calibrate a measurement system or to produce scientific data that can be readily referred to a common base. NIST SP 260 is a catalog of Standard Reference Materials available from NIST.

§ 200.105 Standard reference data.

Data on the physical and chemical properties of the large variety of substances used in science and technology need to be compiled and evaluated for application in research, development, engineering design, and commerce. The Office of Standard Reference Data (OSRD) in the NIST National Measurement Laboratory provides coordination of and access to a number of governmental and nongovernmental data centers throughout this country and the world which are responsive to user needs for data. The OSRD's present program is assembled under a series of tasks which include data for application in energy, environment and health, industrial process design, materials durability, and resource recovery. The subject data are disseminated as hard-copy information in the Journal of Physical and Chemical Reference Data, published jointly with the American Chemical Society and the American Institute of Physics, in the National Standard Reference Data System reports as the NSRDS–NIST series, and as NIST special reports. Magnetic tapes of data on selected topics are also issued through the OSRD and the National Technical Information Service. A newsletter, ''Reference Data Report,'' is issued bimonthly describing current activities. Information concerning the above is available upon request from the OSRD.

§ 200.106 Publications.

Publications provide the primary means of communicating the results of the NIST programs and services to its varied technical audiences, as well as to the general public. NIST issues some

fifteen categories of publications including three periodicals, ten non-periodicals series, interagency reports, and papers in the journals and books of professional organizations, technological associations, and commercial publications. The calibration services, standard reference materials and related measurement services along with changes and fees are published in two Special Publications (SP's) and their supplements. These are SP 250 ''Calibration and Related Measurement Services of the National Institute of Standards & Technology''[1] and SP 260 ''NIST Standard Reference Materials Catalog.''1A complete catalog of all publications by NIST authors is issued annually as a supplement to SP 305 ''Publications of the National Institute of Standards & Technology.'' Announcements and listings of recent NIST publications and services are published in each issue of the bimonthly ''NIST Journal of Research''[2] and the NIST monthly magazine, ''Dimensions/NIST''[2]. Complete citations to NIST publications, along with information on availability are published bimonthly in the ''NIST Publications Newsletter'', available free from the Technical Information and Publications Division, National Institute of Standards & Technology, Washington, DC 20234. NIST publications are also announced (with abstracts) in ''Government Reports Announcements and Index'' published every two weeks by the National Technical Information Service (NTIS), Springfield, Virginia 22161[3]. NTIS also sells microfiche copies of all NIST GPO-published documents, as well as paper copy and microfiche versions of NIST Interagency Reports.

[1] Single copies available free from the National Institute of Standards & Technology, Washington, DC 20234.

[2] For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, for a subscription price. The annual subscription price for the NIST Journal of Research on the date of the publication of these regulations is $13.00 and for Dimensions/NIST it is $11.00. Prices, however, for these publications are subject to change without notice.

[3] The annual subscription rate at the date of the publication of these regulations for this service is $275.00, North American Continent, $375.00 all others.

§ 200.107 WWV–WWVH–WWVB broadcasts.

(a) *Technical services.* The NIST radio stations WWV at Fort Collins, Colorado, and WWVH on the island of Kauai, Hawaii, broadcast a number of technical services continuously night and day. These services are:

(1) Standard radio frequencies, 2.5, 5, 10, 15, and 20, MHz (WWV) and 2.5, 5, 10, and 15 MHz (WWVH); (2) standard time signals; (3) time intervals; (4) UTI corrections; (5) standard audio frequencies; (6) standard musical pitch; (7) a slow time code; (8) Omega Navigation System status reports; (9) geophysical alerts; and (10) marine storm warnings. NIST also broadcasts time and frequency signals from its low frequency station, WWVB, also located at Fort Collins, Colorado.

(2) [Reserved]

(b) *Time announcements.* Once per minute voice announcements are made from WWV and WWVH. The two stations are distinguished by a female voice from WWVH and a male voice from WWV. The WWVH announcement occurs first, at 15 seconds before the minute, while the WWV announcement occurs at 7½ seconds before the minute. Coordinated Universal Time (UTC) is used in these announcements.

(c) *Time corrections.* The UTC time scale operates on atomic frequency, but by means of step adjustments is made to approximate the astronomical UTI scale. It may disagree from UTI by as much as 0.9 second before step adjustments of exactly 1 second are made. These adjustments, or leap seconds are required about once per year and will usually be made on December 31 or June 30. For those who need astronomical time more accurately than 0.9 second, a correction to UTC is encoded by the use of double ticks after the start of each minute. The first through the eighth seconds ticks will indicate a ''plus'' correction, and from the ninth through the 16th a ''minus'' correction. The correction is determined by counting the number of double ticks. For example, if the first, second, and third ticks are doubled, the correction is ''plus'' 0.3 second. If the

ninth, 10th, 11th, and 12th ticks are doubled, the correction is ''minus'' 0.4 second.

(d) *Standard time intervals.* An audio pulse (5 cycles of 1000 Hz on WWV and 6 cycles of 1200 Hz on WWVH), resembling the ticking of a clock, occurs each second of the minute except on the 29th and 59th seconds. Each of these 5-millisecond second pulses occur within a 40-millisecond period, wherein all other modulation (voice or tone) is removed from the carrier. These pulses begin 10 milliseconds after the modulation interruption. A long pulse (0.8 second) marks the beginning of each minute.

(e) *Standard frequencies.* All carrier and audio frequencies occur at their nominal values according to the International System of Units (SI). For periods of 45-second duration, either 500-Hz or 600-Hz audio tones are broadcast in alternate minutes during most of each hour. A 440-Hz tone, the musical pitch A above middle C, is broadcast once per hour near the beginning of the hour.

(f) *Accuracy and stability.* The time and frequency broadcasts are controlled by the NIST atomic frequency standards, which realize the internationally defined cesium resonance frequency with an accuracy of 1 part in 10^{13}. The frequencies transmitted by WWV and WWVH are held stable to better than ±2 parts in 10^{11} at all times. Deviations at WWV are normally less than 1 part in 10^{12} from day to day. Incremental frequency adjustments not exceeding 1 part in 10^{12} are made at WWV and WWVH as necessary. Changes in the propagation medium (causing Doppler effect, diurnal shifts, etc.) result in fluctuations in the carrier frequencies as received which may be very much greater than the uncertainties described above.

(g) *Slow time code.* A modified IRIG H time code occurs continuously on a 100-Hz subcarrier. The format is 1 pulse per second with a 1-minute time frame. It gives day of the year, hours, and minutes in binary coded decimal form.

(h) *Omega announcements.* Omega Navigation System status reports are broadcast in voice from WWV at 16 minutes after the hour and from WWVH at 47 minutes after the hour. The international Omega Navigation System is a very low frequency (VLF) radio navigation aid operating in the 10 to 14 kHz frequency band. Eight stations are in operation around the world. Omega, like other radio navigation systems, is subject to signal degradation caused by ionospheric disturbances at high latitudes. The Omega announcements on WWV and WWVH are given to provide users with immediate notification of such events and other information on the status of the Omega system.

(i) *Geophysical alerts.* These occur in voice at the 18th minute of each hour from WWV. They point out outstanding events which are in process, followed by a summary of selected solar and geophysical events in the past 24 hours and a forecast for the next 24 hours. They are provided by the Space Environment Laboratory, National Oceanic and Atmospheric Administration, Boulder, CO 80303.

(j) *Marine storm information.* Weather information about major storms in the Atlantic and eastern North Pacific are broadcast in voice from WWV at 8, 9, and 10 minutes after each hour. Similar storm warnings covering the eastern and central North Pacific are given from WWVH at 48, 49, and 50 minutes after each hour. An additional segment (at 11 minutes after the hour on WWV and at 51 minutes on WWVH) may be used when there are unusually widespread storm conditions. The brief messages are designed to tell mariners of storm threats in their areas. If there are no warnings in the designated areas, the broadcasts will so indicate. The ocean areas involved are those for which the U.S. has warning responsibility under international agreement. The regular times of issue by the National Weather Service are 0500, 1100, 1700, and 2300 UTC for WWV and 0000, 0600, 1200, and 1800 UTC for WWVH. These broadcasts are updated effective with the next scheduled announcement following the time of issue.

(k) *''Silent'' periods.* These are periods with no tone modulation during which the carrier, seconds ticks, minute time announcements, and 100 Hz modified IRIG H time code continue. They occur during the 16th through the 20th minute on WWVH and the 46th through the 51st minute on WWV.

(l) *WWVB.* This station (antenna coordinates 40°40′28.3″ N., 105°02′39.5″ W.; radiated power 12 kw.) broadcasts on 60 kHz. Its time scale is the same as for WWV and WWVH, and its frequency accuracy and stability are the same. Its entire format consists of a 1 pulse per second special binary time code giving minutes, hours, days, and the correction between its UTC time scale and UTI astronomical time. Identification of WWVB is made by its unique time code and a 45° carrier phase shift which occurs for the period between 10 minutes and 15 minutes after each hour. The useful coverage area of WWVB is within the continental United States. Propagation fluctuations are much less with WWVB than with high-frequency reception, permitting frequency comparisons to be made to a few parts in 10^{11} per day.

(m) *Special Publication 432.* This publication describes in detail the standard frequency and time service of NIST. Single copies may be obtained at no charge upon request from the National Institute of Standards & Technology, Time & Frequency Services Group, 524.06, Boulder, CO 80303. Quantities may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, at a nominal charge per copy.

§ 200.108 Request procedure.

(a) A formal purchase order for the calibration or test should be sent before or at the time the instrument or standard is shipped. The purchase order should provide clear identification of the apparatus being submitted, and give separate instructions for return shipment, mailing of report, and billing. If a customer wishes to minimize the time during which the equipment is out of service, the customer can usually arrange to be notified of the scheduled test date to allow timely shipment. (See § 200.110.) Requests from Federal agencies, or from State agencies, for calibrations or tests on material to be used on private or Federal contract work should be accompanied either by purchase order or by letter or document authorizing the cost of the work to be billed to the agency.

(b) The submission of a purchase order for measurement services under this subchapter shall be understood as constituting an agreement on the part of the customer to be bound by the restrictions on the use of results as set forth in § 200.113 of this part. Acceptance of purchase orders does not imply acceptance of any provisions set forth in the order contrary to the policy, practice, or regulations of NIST or the U.S. Government. (A statement to the effect that NIST is an agency of the U.S. Government should satisfy other Government agencies with regard to compliance with Government regulations and Executive orders.)

(c) A test number will be assigned by NIST to each instrument or group of similar instruments or standards when the order is accepted. This test number should be referred to in all subsequent communications. Also, each instrument in a group must be uniquely identified, usually by the manufacturer's name and instrument serial number. When the serial number is lacking, an alternative identifying mark should be provided. If none is found, NIST will mark the piece with an NIST identification number. If the apparatus submitted has been previously calibrated by NIST, the serial number or identifying mark should be given on the new order, so that a continuing record of stability history can be established.

(d) Inquiries for measurement services should be directed to the NIST address listed in the various sections of the Appendix to SP 250.

§ 200.109 Shipping, insurance, and risk of loss.

(a) Shipment of apparatus to NIST for calibration or other test should be made only after the customer has accepted the estimate of cost and the tentative scheduling. Repairs and adjustments on apparatus submitted should be attended to by the owner, since NIST will not undertake them except by special arrangement. Apparatus not in good condition will not be calibrated. If defects are found after calibration has begun, the effort may be terminated, a report issued summarizing such information as has been found, and a fee charged in accordance with the amount of work done.

(b) The customer should pack apparatus sent to NIST so as to minimize

the likelihood of damage in shipment and handling. Suggestions on packing and shipping are made in some sections of SP 250. In every case, the sender should consider the nature of the apparatus, pack it accordingly, and clearly label shipments containing fragile instruments or materials, such as glass and the like.

(c) To minimize damage during shipment resulting from inadequate packing, the use of strong reusable containers is recommended. As an aid in preventing loss of such containers, the customer's name should be legibly and permanently marked on the outside. In order to prolong the container's use the notation ''REUSABLE CONTAINER, DO NOT DESTROY'' should be marked on the outside.

(d) Shipping and insurance coverage instructions should be clearly and legibly shown on the purchase order for the calibration or test. The customer must pay shipping charges to and from NIST; shipments from NIST will be made collect. The method of return transportation should be stated, and it is recommeded that return shipments be insured, since NIST will not assume liability for their loss or damage. For long-distance shipping it is found that air express and air freight provide an advantage in reduction of time in transit. If return shipment by parcel post is requested or is a suitable mode of transportation, shipments will be prepaid by NIST, but without covering insurance. When no shipping or insurance instructions are furnished, return shipment will be made by common carrier collect, but uninsured.

(e) NIST will not be responsible for the risk of loss or damage to any item during shipment to or from NIST. Any arrangements for insurance covering this risk must be made by the customer. Return shipment will be made by NIST as indicated in paragraph (d) of this section. The purchase order should always show the value of the equipment, and if transit insurance is carried by the customer, this fact should be stated.

(f) The risk of loss or damage in handling or testing of any item by NIST must be assumed by the customer, except when it is determined by NIST that such loss or damage was occasioned solely by the negligence of NIST personnel.

(g) When a test number has been assigned prior to shipment to NIST, this number should be clearly marked on the shipping container. When a test number has not been assigned, an invoice, copy of the purchase order, or letter should be enclosed in the shipment to insure proper identification. The original purchase order should be forwarded as appropriate to:

Office of Measurement Services, National Institute of Standards & Technology, Washington, DC 20234; or to Measurement Services Clerk, National Institute of Standards & Technology, Boulder, CO 80303.

(h) The calibrations listed in SP 250 are performed at Boulder, Colorado and Gaithersburg, Maryland.

§ 200.110 Priorities and time of completion.

Schedule work assignments for calibrations and other tests will generally be made in the order in which confirmed requests are received. However, Government work may be given priority. On the regular services, the workload is usually such that the turnaround interval, between the date a customer's apparatus is received and the date it is prepared for return shipment, will be not more than 45 days. Some types of instruments may require considerably longer, particularly if their abnormal behavior requires reruns to check reliability. The customer who can spare the instrument for only a short time can usually arrange by letter or telephone call for shipping it to NIST just as the assigned starting date approaches. A notice will be sent acknowledging receipt of the customer's standard and/or purchase order. If both a confirmed purchase order (or equivalent) and the apparatus have been received, estimates of the completion date and the calibration fee will be sent upon request.

§ 200.111 Witnessing of operations.

NIST welcomes scientists and engineers who may wish to visit its laboratories and discuss its methods. Ordinarily visitors will not be permitted to witness the actual carrying out of highly precise measurements because their presence introduces distraction

that may lead to errors or delays. This policy may be waived in those cases where NIST determines that the visitor can be of service in setting up apparatus of a new or unusual nature, in the case of referee tests, or in other cases in which the legal validity of the result may require the presence of duly authorized witnesses.

§ 200.112 Reports.

(a) Results of calibrations and other tests are issued to the customer as formal reports entitled, ''National Institute of Standards & Technology Report of Calibration,'' ''National Institute of Standards & Technology Report of Test,'' or ''National Institute of Standards & Technology Report of Analysis,'' as appropriate. Copies are not supplied to other parties except under applicable Federal law. Whenever formal certification is required by law, or to meet special conditions adjudged by NIST to warrant it, a letter will be provided certifying that the particular item was received and calibrated or tested, and identifying the report containing the results.

(b) NIST reports of calibration generally include in sentence form a statement of the uncertainty attached to the numerical values reported. Limits of uncertainty usually comprise an estimate of systematic error plus a value of imprecision. Details on how these estimates are arrived at are in many cases included in the calibration report. Additional information may be found in SP 250.

(c) The NIST practice is to express data given in calibration or test reports in the SI or International System of Units. The International System of Units (SI) was defined and given official status by the 11th General Conference of Weights and Measures, 1960. A complete listing of SI units is presented in detail in NIST SP 330. The NIST will express data in SI units unless this makes communication excessively complicated. For example, commercial gage designations, commonly used items identified by nominal dimensions, or other commercial nomenclatures or devices (such as drill sizes, or commercial standards for weights and measures) expressed in customary units are an exception from this practice. However, even in such instances, when practical and meaningful, SI and customary units may be given in parallel. Users of NIST calibration services may specify the units to be used in the calibration, especially for commercial devices and standards using customary units or units having some legal definition.

§ 200.113 Use of results or reports.

(a) As the national standards laboratory of the United States, NIST maintains and establishes the primary standards from which measurements in science and industry ultimately derive. It is therefore sometimes desirable for manufacturers or users of measurement standards to make appropriate reference to the relationship of their calibrations to NIST calibrations. The following considerations must be borne in mind, and shall be understood as constituting an agreement on the part of the NIST customer to be bound thereby in making reference to NIST calibration and test reports.

(b) The results of calibrations and tests performed by NIST are intended solely for the use of the organization requesting them, and apply only to a particular device or specimen at the time of its test. The results shall not be used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that NIST approves, recommends, or endorses the manufacturer, the supplier, or the user of such devices or specimens, or that NIST in any way ''guarantees'' the later performance of items after calibration or test.

(c) NIST declares it to be in the national interest that it maintain an impartial position with respect to any commercial product. Advertising the findings on a single instrument could be misinterpreted as an indication of performance of other instruments of identical or similar type. There will be no objection, however, to a statement that the manufacturer's primary standards have been periodically calibrated by NIST, if this is actually the case, or that the customer might arrange to have NIST calibrate the item purchased from the manufacturer.

(d) NIST does not approve, recommend, or endorse any proprietary product or proprietary material. No reference shall be made to NIST, or to reports or results furnished by NIST in any advertising or sales promotion which would indicate or imply that NIST approves, recommends, or endorses any proprietary product or proprietary material, or which has as its purpose an intent to cause directly or indirectly the advertised product to be used or purchased because of NIST test reports or results.

In its own activities as a scientific institution, NIST uses many different materials, products, types of equipment, and services. This use does not imply that NIST has given them a preferential position or a formal endorsement. Therefore, NIST discourages references, either in advertising or in the scientific literature, which identify it as a user of any proprietary product, material, or service. Occasionally, effective communication of results by NIST to the scientific community requires that a proprietary instrument, product, or material be identified in an NIST publication. Reference in an NIST publication, report, or other document to a proprietary item does not constitute endorsement or approval of that item and such reference should not be used in any way apart from the context of the NIST publication, report, or document without the advance express written consent of NIST.

§ 200.114 Fees and bills.

(a) In accordance with 15 U.S.C. 271 *et seq.*, fees are charged for all measurement services performed by NIST, unless waived by the Director, or the Director's designee, when deemed to be in the interest of the Government. The above-mentioned statutes authorize the issuance from time to time of appropriate regulations regarding the payment of fees, the limits of tolerance on standards submitted for verification, and related matters.

(b) The minimum fee for any service request accepted by NIST is $10, unless otherwise indicated in SP 250. If apparatus is returned without testing, a minimum charge of $10 may be made to cover handling. Charges commensurate with the work performed will be assessed for calibrations which cannot be completed because of faulty operation of the customer's device. Fees for calibrations or tests include the cost of preparation of an NIST report. Remittances should be made payable to the National Institute of Standards & Technology.

§ 200.115 Description of services and list of fees, incorporation by reference.

(a) NIST Special Publication 250, ''Calibration and Related Measurement Services of the National Institute of Standards & Technology'' is hereby incorporated by reference, pursuant to 5 U.S.C. 552(a)(1) and 1 CFR Part 51. SP 250 states the authority under which NIST performs various types of measurement services including calibrations and tests and charges fees therefor, states the general conditions under which the public may secure such services, decribes these services in considerable detail, and lists the fees to be charged, and sets out the instructions for requesting them in an appendix which is reviewed, revised and reissued semi-annually (December and June). The Director, Office of the Federal Register, approved the incorporation by reference on December 28, 1967.

(b) SP 250 is available at the following places:

(1) Superintendent of Documents, Government Printing Office, Washington, DC 20402.

(2) Technical Information and Publications Division, National Institute of Standards & Technology, Washington, DC 20234.

(3) District Offices of the U.S. Department of Commerce.

(4) Federal Depository Libraries.

(c) Revisions of SP 250 will be issued from time to time by the National Institute of Standards & Technology, Washington, DC 20234.

(d) Further information concerning policies, procedures, services, and fees may be obtained by writing the Office of Measurement Services, National Institute of Standards & Technology, Washington, DC 20234.

SUBCHAPTER B—STANDARD REFERENCE MATERIALS

PART 230—STANDARD REFERENCE MATERIALS

Subpart A—General Information

Subpart B—Purchase Procedure

Subpart C—Description of Services and List of Fees

AUTHORITY: Sec. 9, 31 Stat. 1450, as amended; 15 U.S.C. 277. Interprets and applies sec. 7, 70 Stat. 959; 15 U.S.C. 275a.

SOURCE: 41 FR 8472, Feb. 27, 1976, unless otherwise noted.

Subpart A—General Information

§ 230.1 Introduction.

This part states the procedure for ordering Standard Reference Materials (SRM's) issued by the National Institute of Standards & Technology. SRM's are used to calibrate measurement systems, evaluate measurement methods, or produce scientific data that can be referred to a common base. NIST Special Publication 260, ''Catalog of NIST Standard Reference Materials,'' lists and describes the SRM's issued by NIST. SP 260 is periodically revised to include new SRM's and eliminate those that have been discontinued. Between editions of SP 260, supplements are issued that list new or renewal SRM's not listed in SP 260. In addition, these supplements list the fees charged for available SRM's.

[41 FR 8472, Feb. 27, 1976, as amended at 55 FR 38315, Sept. 18, 1990]

§ 230.2 Identification of Standard Reference Materials.

The SRM's are listed by category in SP 260 and by sequential number in the supplements. The number uniquely identifies a particular SRM. Renewals are indicated by the addition of a letter to the original number. Thus, 11a is the first, 11b the second, and 11c the third renewal of SRM 11, Basic Open-Hearth Steel, 0.2 percent carbon. In this way, a particular number or number and letter always represent a material of fixed or approximately fixed composition.

§ 230.3 New Standard Reference Materials.

When new SRM's or renewals of old ones are issued, announcements are made in SP 260, its supplement, and in scientific and trade journals.

Subpart B—Purchase Procedure

§ 230.4 Ordering.

Orders should be addressed to the Office of Standard Reference Materials, National Institute of Standards & Technology, Washington, DC 20234. Orders should give the amount (number of units), catalog number and name of the standard requested. *For example:* 1 each, SRM 11h, Basic Open-Hearth Steel, 0.2 percent C. These materials are distributed only in the units listed.

[41 FR 8472, Feb. 27, 1976, as amended at 55 FR 38315, Sept. 18, 1990]

§ 230.5 Terms and shipping.

(a) Prices are given in the SP 260 supplement. These prices are subject to revision and orders will be billed for prices in effect at the time of shipment. No discounts are given on purchases of SRM's.

(b) Payment need not accompany a purchase order. Payment is due within 30 days of receipt of an invoice.

(c) SRM's are shipped in the most expeditious manner that complies with transportation and postal laws and regulations.

§ 230.6 Standard Reference Materials out of stock.

Orders for out-of-stock SRM's will be returned with information as to future availability.

Subpart C—Description of Services and List of Fees

§ 230.7 Description of services and list of fees, incorporation by reference.

(a) The text of NIST Special Publication 260, ''Catalog of NIST Standard Reference Materials,'' and its supplement are hereby incorporated by reference pursuant to 5 U.S.C. 552(a)(1) and 1 CFR Part 51.

(b) SP 260 describes the SRM's that are available and states the procedure for ordering the materials. SP 260 is available at the following places:

Superintendent of Documents, Government Printing Office, Washington, DC 20402.

Office of Standard Reference Materials, National Institute of Standards & Technology, Washington, DC 20234.

(c) Supplements are issued when needed to reflect additions, deletions, and corrections to SP 260, and to list fees charged for the SRM's. Supplements are available from the Office of Standard Reference Materials, National Institute of Standards & Technology, Washington, DC 20234.

[41 FR 8472, Feb. 27, 1976, as amended at 55 FR 38315, Sept. 11, 1990]

SUBCHAPTER C—TRANSCRIPT SERVICES [RESERVED]
SUBCHAPTER D—STANDARDS FOR BARRELS

PART 240—BARRELS AND OTHER CONTAINERS FOR LIME

Sec.

AUTHORITY: Sec. 4, 39 Stat. 531; 15 U.S.C. 240.

SOURCE: 13 FR 8372, Dec. 28, 1948, unless otherwise noted.

§ 240.1 Title of act.

The act, ''Pub. L. 228, 64th Congress,'' approved August 23, 1916 (39 Stat. 530; 15 U.S.C. 237–242), entitled ''An Act to standardize lime barrels,'' shall be known and referred to as the ''Standard Lime-Barrel Act.''

§ 240.2 Application.

The rules and regulations in this part are to be understood and construed to apply to lime in barrels, or other containers packed, sold, or offered for sale for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia; and to lime in containers of less capacity than the standard small barrel sold in interstate or foreign commerce; and to lime imported in barrels from a foreign country and sold or offered for sale; also to lime not in barrels or containers of less capacity than the standard small barrel, sold, charged for, or purported to be delivered as a large or small barrel or a fractional part of said small barrel of lime, from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia.

§ 240.3 Permissible sizes.

Lime in barrels shall be packed only in barrels containing 280 pounds or 180 pounds, net weight. For the purposes of this section the word ''barrel'' is defined as a cylindrical or approximately cylindrical vessel, cask or drum.

(Sec. 2, 39 Stat. 530; 15 U.S.C. 238)

§ 240.4 Definitions.

(a) The term *container of less capacity than the standard small barrel,* as mentioned in section 3 of the law and as used in the rules and regulations in this part, is defined as any container not in barrel form containing therein a net weight of lime of less than 180 pounds.

(b) The term *label* as used in the rules and regulations in this part is defined as any printed, pictorial, or other matter upon the surface of a barrel or other container of lime subject to the provisions of this act, or upon cloth or paper or the like which is permanently affixed to it by pasting or in a similar manner.

(c) The term *tag* is defined as a tough and strong strip of cloth or paper or the like, bearing any printed, pictorial, or other matter, which is loose at one end and which is secured to a container of lime subject to the provisions of the act.

(Sec. 3, 39 Stat. 530; 15 U.S.C. 239)

§ 240.5 Required marking.

(a) The lettering required upon barrels of lime by section 2 of the law shall be as follows: The statement of net weight shall be in boldface capital letters and figures at least 1 inch in height and not expanded or condensed; it shall be clear, legible, and permanent, and so placed with reference to the other lettering that it is conspicuous. The name of the manufacturer of the lime and where manufactured, and, if imported, the name of the country from which it is imported, shall be in boldface letters at least one-half inch in height and not expanded or condensed, and shall be clear, legible, conspicuous, and permanent. None of these letters and figures shall be superimposed upon each other, nor shall any other characters be superimposed upon the required lettering or otherwise obscure it. All the above statements shall form parts of the principal label.

(b) The information required upon containers of lime of less capacity than the standard small barrel by section 3 of the law shall be included in a label: *Provided, however,* That in order to allow the utilization of second-hand or returnable bags made of cloth, burlap, or the like, such information may be upon a tag firmly attached to the container in a prominent and conspicuous position. In case a tag is used to give the required information there must not be any label or another tag upon the container which bears any statement having reference to lime, or any statement of weight whatever, which is not identical with the information upon the tag mentioned above; if a container is to be utilized which bears any such inaccurate information upon a label, such container shall be turned inside out or such information shall be obliterated in so far as it is inaccurate by blotting out the letters or figures; or if such inaccurate information is upon a tag, by removing such tag.

(c) If the required lettering is upon a label, the statement of net weight shall be in bold-face capital letters and figures at least three-fourths inch in height and not expanded or condensed; it shall be clear, legible, and permanent, and so placed with reference to the other lettering that it is conspicuous. The word ''net'' shall form part of the statement of weight. The name of the manufacturer of the lime and the name of the brand, if any, under which it is sold, and, if imported, the name of the country from which it is imported, shall be in bold face letters at least one-half inch in height and not expanded or condensed, and shall be clear, legible, conspicuous, and permanent. None of these letters and figures shall be superimposed upon each other, nor shall any other characters be superimposed upon the required lettering or otherwise obscure it. All the above statements shall form parts of the principal label.

(d) If the required lettering is upon a tag, the statement of net weight shall be in bold-face capital letters and figures not less than one-half the height of the largest letters or figures used upon such tag: *Provided, however,* That in every case they shall be not less than one-eighth inch in height (12–point capitals), and not expanded or condensed. The word ''net'' shall form part of the statement of weight. The statement shall be clear, legible, and permanent, and so placed with reference to the other lettering that it is conspicuous. The name of the manufacturer of the lime, and the name of the brand, if any, under which it sold, and, if imported, the name of the country from which it is imported, shall be in bold-face letters and figures not less than one-eighth inch in height (12–point capitals), and not expanded or condensed, and shall be clear, legible, conspicuous, and permanent. None of these letters and figures shall be superimposed upon each other nor shall any other characters be superimposed upon the required lettering or otherwise obscure it. All the above statements shall be included upon the same side of the tag.

(e) In case the lime is actually packed in barrels or in containers of less capacity than the standard small barrel by some person other than the manufacturer of the lime, the information mentioned above must be given in the manner there described, and in addition there must be a statement to this effect: ''Packed by ———— ————'' (giving the name and address of the packer). This statement shall be in letters not smaller than is specified for the general statement required in the case of barrels and containers of less capacity than the standard small barrel, respectively (see paragraphs (a) and (b) of this section); it shall not be obscured and shall form part of the principal label or be upon the same side of the tag as in those cases provided.

(f) In the case of all lime sold in barrels, the actual place of manufacture of the lime shall be stated on the barrel. In general, this will be the name of the post office nearest or most accessible to the plant. However, when the actual place of manufacture of the lime and the offices of the company are separated but are within the boundaries of the same county of a State, or when, though not within the boundaries of the same county they are so close together that the post-office address of the offices represents substantially and to all intents and purposes the actual

place of manufacture of the lime, then the post-office address of the offices of the company will be sufficient: *Provided, however,* That the address given shall always correctly show the State in which the lime is actually manufactured.

(g) More than one place of manufacture of a manufacturer shall not be shown on the same barrel unless the one at which the particular lime in question is manufactured is pointed out.

(h) If the location of the home offices is stated and this is not the place of manufacture within the meaning of the above definition, an additional statement must be included to this effect: ''Manufactured at ————'' (giving the location of the plant).

(Secs. 2, 3, 39 Stat. 530; 15 U.S.C. 238, 239)

§ 240.6 Tolerances.

(a) When lime is packed in barrels the tolerance to be allowed on the large barrel or the small barrel of lime shall be 5 pounds in excess or in deficiency on any individual barrel: *Provided, however,* That the average error on 10 barrels of the same nominal weight and packed by the same manufacturer shall in no case be greater than 2 pounds in excess or in deficiency. In case all the barrels available are not weighed, those which are weighed shall be selected at random.

(b) When lime is packed in containers of less capacity than the standard small barrel, the tolerance to be allowed in excess or in deficiency on individual containers of various weights, shall be the values given in the column headed ''Tolerance on individual package,'' of the following table: *Provided, however,* That the average error on 10 containers of the same nominal weight and packed by the same manufacturer shall in no case be greater than the values given in the column headed ''Tolerance on average weight,'' of the following table. In case all the containers available are not weighed, those which are weighed shall be selected at random.

Weight of packaged	Tolerance on individual package (pounds)	Tolerance on average weight (pounds)
Not greater than 50 lbs	1½	⅝
More than 50 lb. and not greater than 100 lbs	2	¾
More than 100 lb. and not greater than 150 lb	3	1¼
More than 150 lb. and less than 180 lb	4	1½

(c) When lime in bulk is sold, charged for, or purported to be delivered as a definite number of large or small barrels, the tolerance to be allowed in excess or in deficiency on such amounts of lime shall be 15 pounds per 1,800 pounds (10 small barrels), or 25 pounds per 2,800 pounds (10 large barrels).

PART 241—BARRELS FOR FRUITS, VEGETABLES AND OTHER DRY COMMODITIES, AND FOR CRANBERRIES

Sec.

AUTHORITY: Sec. 3, 38 Stat. 1187; 15 U.S.C. 236.

SOURCE: 13 FR 8373, Dec. 28, 1948, unless otherwise noted.

NOTE: The rules and regulations in this part refer entirely to individual barrels, and no separate tolerance has been placed on the average content of a number of barrels taken at random from a shipment. It is not believed that barrels can be so made as to take advantage of the tolerances, and, of course, no attempt should be made to do this. It is, therefore, expected that as many barrels will be above as below the standard capacity.

§ 241.1 Capacities.

(a) The capacities of the standard barrel for fruits, vegetables, and other dry commodities, other than cranberries, and its subdivisions, are as follows:

Size	Cubic inches	Bushels [1]	Quarts [1]
Barrel	7,056	3.281	105
¾ barrel	5,292	2.46	78¾
½ barrel	3,528	1.641	52½
⅓ barrel	2,352	1.094	35

[1] Struck measure.

(b) The capacities of the standard cranberry barrel and its subdivisions are as follows:

Size	Cubic inches	Bushels [1]	Quarts [1]
Cranberry barrel	5,826	2.709	86 45/64
¾ cranberry barrel	4,369.5	2.032	65 1/64
½ cranberry barrel	2,913	1.355	43 11/32
⅓ cranberry barrel	1,942	.903	28 29/32

[1] Struck measure.

(Sec. 1, 38 Stat. 1186; 15 U.S.C. 234)

§241.2 Legal standard barrels.

(a) Any barrel having the dimensions specified for a standard barrel for fruits, vegetables, and other dry commodities, other than cranberries, in section 1 of the standard-barrel law, or any barrel or a subdivision thereof having the contents specified in section 1 of the standard-barrel law and in §241.1(a) regardless of its form or dimensions, is a legal standard barrel for fruits, vegetables, or other dry commodities other than cranberries, or a legal subdivision thereof. No other barrel or subdivision in barrel form is a legal container for fruits, vegetables, or other dry commodities other than cranberries.

(b) Any barrel having the dimensions specified for a standard barrel for cranberries in section 1 of the standard-barrel law, or any subdivision thereof having the contents specified in §241.1(b), regardless of its form or dimensions, is a legal standard barrel for cranberries or a legal subdivision thereof. No other barrel or subdivision in barrel form is a legal container for cranberries.

(Sec. 1, 38 Stat. 1186; 15 U.S.C. 234)

§241.3 Application of tolerance for "distance between heads."

The tolerance established in this part for the dimension specified as ''distance between heads'' shall be applied as follows on the various types of barrels in use:

(a) When a barrel or subdivision thereof has two heads, the tolerance shall be applied to the distance between the inside surfaces of the heads and perpendicular to them.

(b) When a barrel or subdivision thereof has but one head and a croze ring or other means for the insertion of a head, such as an inside hoop, etc., at the opposite end, the tolerance shall be applied to the distance from the inside surface of the bottom head and perpendicular to it to the inside edge of the croze ring, or to a point where the inside surface of a head would come were such head inserted in the barrel.

(c) When a barrel or subdivision thereof has but one head and no croze ring or other means for the insertion of a head, such as an inside hoop, etc., at the opposite end, the tolerance shall be applied to the distance from the inside surface of the bottom head and perpendicular to it to a point 1⅛ inches from the opposite end of the staves in the case of a barrel or a ¾ barrel, and to a point 1 inch or ⅞ inch from the opposite end of the staves in the case of the ½ barrel and ⅓ barrel, respectively. When a barrel or subdivision thereof has been manufactured with but one head and no croze ring or other means for the insertion of a head at the opposite end, and it is desired to insert a second head, the croze ring shall be so cut that the inside edge shall not be more than 1⅛ inches from the end of the staves in the case of a barrel or ¾ barrel or not more than 1 inch or ⅞ inch from the end of the staves in the case of the ½ barrel and ⅓ barrel, respectively, or the other means shall be so adjusted that the inside surface of the head when inserted shall not exceed these distances from the end of the staves.

§241.4 Application of tolerance for "diameter of head."

(a) The tolerance established in this part for the dimension specified as ''diameter of head'' shall be applied to the diameter of the head over all, including the part which fits into the croze ring of the completed barrel.

(b) The tolerance established in this part for the dimension specified as ''effective diameter of head'' shall be applied as follows on the various types of barrels and subdivisions in use;

(1) When a barrel or subdivision thereof has two heads, the tolerance shall be applied to the mean of the average diameters from inside to inside of staves at the inner edges of the heads.

(2) When a barrel or subdivision thereof has but one head and a croze ring or other means for the insertion of a head at the opposite end, the tolerance shall be applied to the mean of the average diameters, one taken from inside to inside of staves at the inner edge of the head, the other from inside to inside of staves at the inner edge of the croze ring, or from inside to inside of staves at a point where the inside surface of a head would come were such head inserted in the barrel.

(3) When a barrel or subdivision thereof has but one head and no croze ring or other means for the insertion of a head at the opposite end, the tolerance shall be applied to the mean of the average diameters, one taken from inside to inside of staves at the inner edge of the head, the other taken from inside to inside of staves at a point 1⅛ inches from the end of the staves in the case of a barrel or ¾ barrel, or at a point 1 inch or ⅞ inch from the end of the staves in the case of a ½ barrel or ⅓ barrel, respectively.

(c) The standard allowance for depth of croze ring shall be 3/16 inch. Therefore, the standard ''effective diameter of head'' in the case of the standard barrel is 16¾ inches and in the case of the standard cranberry barrel is 15⅞ inches.

§ 241.5 Standard dimensions.

Whenever in the rules and regulations in this part the error on a dimension is mentioned, this error shall be determined by taking the difference between the actual measured dimension and the standard dimension. The error is an error in excess and is to be preceded by a plus sign when the measured dimension is greater than the standard dimension. The error is an error in deficiency and is to be preceded by a minus sign when the measured dimension is less than the standard dimension.

(a) The standard dimensions of a barrel for fruits, vegetables, and other dry commodities other than cranberries, and of a barrel for cranberries, with which the actual measured dimensions are to be compared, are as follows:

Dimensions	Barrel for fruits, vegetables, and other dry commodities other than cranberries (inches)	Barrel for cranberries (inches)
Diameter of head	17⅛	16¼
Effective diameter of head (see § 241.4)	16¾	15⅞
Distance between heads	26	25¼
Circumference of bulge, outside measurement	64	58½
Length of stave	28½	28½

(b) In the case of all subdivisions of the barrel for fruits, vegetables, and other dry commodities other than cranberries, and all subdivisions of the barrel for cranberries, the following dimensions are hereby standardized for the purpose of the application of tolerances, and the actual measured dimensions are to be compared with these:

SUBDIVISIONS OF BARREL FOR FRUITS, VEGETABLES, AND OTHER DRY COMMODITIES OTHER THAN CRANBERRIES

Dimensions	¾ barrel (inches)	½ barrel (inches)	⅓ barrel (inches)
Effective diameter of head (see § 241.4)	15¼	13⅜	11⅝
Distance between heads	23½	20½	18
Circumference of bulge, outside measurement	58½	51½	45¼

SUBDIVISIONS OF BARREL FOR CRANBERRIES

Effective diameter of head (see § 241.4)	14⅜	12⅝	11
Distance between heads	23	20	17½
Circumference of bulge, outside measurement	53⅜	47	41⅜

(Sec. 1, 38 Stat. 1186; 15 U.S.C. 234)

§ 241.6 Classes of barrels for tolerance application.

For the purpose of the application of tolerances, barrels for fruits, vegetables, and other dry commodities other than cranberries, are hereby divided into two classes as follows:

(a) Class 1 shall include (1) all barrels no dimension of which is in error by more than the following amounts, and

(2) all barrels one or more of the dimensions of which are in error by more than the following amounts, and which in addition have no dimension in error in the opposite direction:

	Error, inches
Effective diameter of head	¼
Distance between heads	¼
Circumference of bulge, outside measurement	1½

(b) Class 2 shall include all barrels at least one dimension of which is in error by more than the amounts given above, but which in addition have at least one dimension in error in the opposite direction. (This class includes all barrels mentioned in section 1 of the law in the proviso reading: ''*Provided,* That any barrel of a different form having a capacity of seven thousand and fifty-six cubic inches shall be a standard barrel.'')

(Sec. 1, 38 Stat. 1186; 15 U.S.C. 234)

§241.7 Tolerances to be allowed.

(a) The tolerances to be allowed in excess or in deficiency on the dimensions of all barrels of Class 1 shall be as follows:

	Tolerance inches
Diameter of head	¼
Effective diameter of head	¼
Distance between heads	¼
Circumference of bulge, outside measurement	1½
Length of stave	½

(1) If no dimension of a barrel of Class 1 is in error by more than the tolerance given above, then the barrel is within the tolerance allowed.

(2) If one or more of the dimensions of a barrel of Class 1 is in error by more than the tolerance given above, then the barrel is not within the tolerance allowed.

(b) The tolerance to be allowed in excess or in deficiency on all barrels of Class 2 shall be 1½ inches (1.5) inches, and this tolerance is to be applied to the result obtained by the application of the following rule:

(1) Having determined the errors of each dimension and given to each its proper sign (see §241.4), add the errors on the effective diameter of head and the distance between heads algebraically and multiply the result by 1.67 (or 5/3). Then add this result to the error on the circumference of bulge algebraically. If the result obtained is not greater than the tolerance given above, then the barrel is within the tolerance allowed; if the result is greater than this tolerance, then the barrel is not within the tolerance allowed.

NOTE: To find the algebraic sum of a number of quantities having different signs, first add all those having one sign; then add all those having the opposite sign; then subtract the smaller sum from the larger, giving this result the sign of the larger quantity.

(2) [Reserved]

(c) The tolerance to be allowed in excess or in deficiency on the dimensions of all barrels for cranberries shall be as follows:

	Tolerance, inches
Diameter of head	¼
Effective diameter of head	¼
Distance between heads	¼
Circumference of bulge, outside measurement	1⅜
Length of stave	½

(1) If no dimension of a barrel for cranberries is in error by more than the tolerance given above, then the barrel is within the tolerance allowed.

(2) If one or more of the dimensions of a barrel for cranberries is in error by more than the tolerance given above, then the barrel is not within the tolerance allowed.

(d) The tolerances to be allowed in excess or in deficiency on all subdivisions of the standard barrel for fruits, vegetables, and other dry commodities other than cranberries, and on all subdivisions of the standard barrel for cranberries, shall be the values given in the following table, and these tolerances are to be applied to the result obtained by the application of the following rule:

(1) Having determined the errors on each dimension and given to each its proper sign (see §241.5), add the errors on the effective diameter of head and the distance between heads algebraically and multiply the result by 1.67 (or 5/3). Then add this result to the error on the circumference of bulge algebraically. If the result obtained is not greater than the tolerance given in the following table for the proper subdivision, then the barrel is within the tolerance allowed; if the result is

greater than this tolerance, then the barrel is not within the tolerance allowed.

Size of subdivision	Tolerance	
	For fruits, vegetables, and other dry commodities (inches)	For cranberries (inches)
¾ barrel	1⅜ (1.375)	1¼ (1.25)
½ barrel	1¼ (1.25)	1⅛ (1.125)
⅓ barrel	1⅛ (1.125)	1 (1.00)

SUBCHAPTER E—FELLOWSHIPS AND RESEARCH ASSOCIATES

PART 255—FELLOWSHIPS IN LABORATORY STANDARDIZATION AND TESTING FOR QUALIFIED CITIZENS OF OTHER AMERICAN REPUBLICS

Sec.

AUTHORITY: R.S. 161; sec. 1, 53 Stat. 1290; 22 U.S.C. 501.

SOURCE: 13 FR 8374, Dec. 28, 1948, unless otherwise noted.

§ 255.1 Type of fellowships.

Fellowships shall be of the combined intern-training and training-in-research type, and may include any or all of the following courses:

(a) Orientation courses consisting of lectures and conferences at the National Institute of Standards & Technology pertaining to laboratory standardization and testing.

(b) Practical laboratory training in various branches of physics, chemistry, and engineering research, under the direction of the National Institute of Standards & Technology, which will include the usual subdivisions of physics (weights and measures, heat, optics, mechanics, atomic physics, electrical measurements and radio) and also technologic applications in research and testing on metals, rubber, leather, paper, textiles, plastics, and clay and silicate products.

(c) Observation and study in such other laboratories within the continental United States as may be selected by the Director of the National Institute of Standards & Technology.

(d) Courses of instruction or research assignments supplementing the practical laboratory training, in universities or colleges selected by the Director of the National Institute of Standards & Technology.

[13 FR 8374, Dec. 28, 1948, as amended at 55 FR 38315, Sept. 18, 1990]

§ 255.2 Qualifications.

Each applicant selected for a fellowship shall be:

(a) A citizen of an American republic other than the United States;

(b) In possession of a certificate of medical examination issued by a licensed physician within 60 days of the date of application, describing the applicant's physical condition and stating that he is free from any communicable disease, physical deformity or disability that would interfere with the proper pursuit of training, research, or any other activity or work incident to the fellowship;

(c) Able to speak, read, write and understand the English language;

(d) Of good moral character and possessing intellectual ability and suitable personal qualities; and

(e) In possession of acceptable evidence that he has successfully completed the equivalent of a four-year university course in a recognized university, college or other institution of learning, with some training or experience in the field of activity which he desires to pursue. Equivalent experience may be substituted for the university training in the case of candidates who are otherwise specially well qualified.

§ 255.3 Award of fellowships.

Fellowships shall be awarded by the Director of the National Institute of Standards & Technology, with the approval of the Secretary of Commerce and the Secretary of State, or the duly authorized representative of the Secretary of State. Applications shall be transmitted to the Secretary of State by the government of the American republic of which the applicant is a citizen through the American diplomatic mission accredited to that government.

[13 FR 8374, Dec. 28, 1948, as amended at 55 FR 38315, Sept. 18, 1990]

§ 255.4 Allowances and expenses.

Allowances and expenses shall be as provided in State Department regulations given in 22 CFR Part 61, and as

provided in Department of Commerce Administrative Order No. 202–3.[1]

§ 255.5 Progress reports.

Applicants awarded fellowships under the regulations in this part shall submit written reports of progress in training and research at such intervals as the Director of the National Institute of Standards & Technology may determine.

[13 FR 8374, Dec. 28, 1948, as amended at 55 FR 38316, Sept. 18, 1990]

§ 255.6 Duration of fellowships.

Fellowships may be awarded for periods of varying length, not exceeding one 12–month period of actual training and research and may be extended for not exceeding the same periods in the manner prescribed under § 255.3 and subject to the availability of appropriations. Fellowships may be cancelled for cause by the Director of the National Institute of Standards & Technology, with the approval of the Secretary of Commerce and the Secretary of State, or the duly authorized representative of the Secretary of State.

[13 FR 8374, Dec. 28, 1948, as amended at 55 FR 38316, Sept. 18, 1990]

§ 255.7 Official notification.

Each applicant selected by the Director of the National Institute of Standards & Technology and approved by the Secretary of Commerce and the Secretary of State, or the duly authorized representative of the Secretary of State, shall be notified of his award through diplomatic channels. The notification shall state the duration and type of fellowship, outline the program of training and research, and state the allowances authorized: *Provided, however,* That the Director of the National Institute of Standards & Technology may subsequently amend the program and duration of the fellowship if in his opinion such action would be in the interest of obtaining training and research better suited to the needs and capabilities of the fellow than those prescribed in the notification. The amount originally authorized for monthly allowances and other expenses may also be amended, if necessary, with the approval of the Secretary of Commerce and the Secretary of State, or the duly authorized representative of the Secretary of State.

[13 FR 8374, Dec. 28, 1948, as amended at 55 FR 38316, Sept. 18, 1990]

[1] Not filed with the Office of the Federal Register.

PART 256—RESEARCH ASSOCIATE PROGRAM

Sec.
256.1 Introduction.
256.2 The Research Associate Program.
256.3 Procedure.
256.4 Qualifications.
256.5 Duration of projects.
256.6 Information concerning the Research Associate Program.

AUTHORITY: 27 Stat. 395, 31 Stat. 1039; 20 U.S.C. 91.

SOURCE: 32 FR 10252, July 12, 1967, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 256 appear at 55 FR 38316, Sept. 18, 1990.

§ 256.1 Introduction.

This part states policies and procedures concerning the Research Associate Program at the National Institute of Standards & Technology. In the exercise of its functions as a major scientific agency of the Federal Government, the National Institute of Standards & Technology may make its facilities available to persons other than Bureau employees to work with scientists and engineers in collaborative research aimed at furthering the Nation's scientific, industrial, and economic growth. Such cooperative programs may be sponsored by professional, technical, or industrial organizations or associations. Such participants, when so sponsored, are designated ''Research Associates''.

§ 256.2 The Research Associate Program.

The Bureau provides its facilities, scientific competence, and technical supervision for defined scientific or technical research by a Research Associate when such research is complementary to and compatible with scientific or technical research being performed or to be undertaken by NIST

under its statutory mission and authority. The Sponsors pay the salaries of their Research Associates and Sponsor-furnished technical assistants and secretaries of the Research Associates, if any, their travel costs, and other related expenses. Additionally, Sponsors reimburse NIST for the cost of research equipment, services, or materials obtained for the Research Associate.

[32 FR 10252, July 12, 1967, as amended at 40 FR 50707, Oct. 31, 1975]

§ 256.3 Procedure.

Arrangements for collaborative research by NIST with a Research Associate generally begin through discussions or correspondence between NIST scientists and representatives of potential sponsoring companies, trade associations or professional organizations. These preliminary steps are followed by the consummation of a Memorandum of Agreement which is signed by NIST, the sponsoring organization and the Research Associate. The agreement sets out the respective responsibilities and obligations of all parties.

§ 256.4 Qualifications.

Each candidate selected to serve as a Research Associate must be determined to be scientifically qualified by the Sponsor and by the NIST, and found by NIST to be of good moral character and to possess suitable personal qualities.

§ 256.5 Duration of projects.

The work of a Research Associate is generally conducted on a full-time basis. Typically, Research Associates are in residence at NIST for 6 to 18 months; longer-term programs may be carried on by a succession of Research Associates. Agreements provide for cancellation by any of the parties.

§ 256.6 Information concerning the Research Associate Program.

Information concerning the Research Associate Program may be obtained from the Industrial Liaison Officer, National Institute of Standards & Technology, Washington, DC 20234.

[40 FR 50707, Oct. 31, 1975]

SUBCHAPTER F—REGULATIONS GOVERNING TRAFFIC AND CONDUCT

PART 265—REGULATIONS GOVERNING TRAFFIC AND CONDUCT ON THE GROUNDS OF THE NATIONAL INSTITUTE OF STANDARDS & TECHNOLOGY, GAITHERSBURG, MARYLAND, AND BOULDER AND FORT COLLINS, COLORADO

Subpart A—General

Subpart B—Traffic and Vehicular Regulations

Subpart C—Buildings and Grounds

Subpart D—Penalties

AUTHORITY: Sec. 9, 31 Stat. 1450, as amended (15 U.S.C. 277). Applies sec. 1, 72 Stat 1711, as amended, (15 U.S.C. 278e(b)).

SOURCE: 39 FR 41170, Nov. 25, 1974, unless otherwise noted.

Subpart A—General

§ 265.1 Definitions.

As used in this part:

(a) *Site* means those grounds and facilities of the National Institute of Standards & Technology, Department of Commerce located in Montgomery County, Maryland, and in Boulder and Larimer Counties, Colorado, over which the Federal Government has acquired concurrent jurisdiction in accordance with appropriate authority.

(b) *Uniformed guard* means a designated employee appointed by the Director for purposes of carrying out the authority of a U.S. Special Policeman, as provided by 40 U.S.C. 318.

(c) *Director* means the Director of the National Institute of Standards & Technology.

[39 FR 41170, Nov. 25, 1974, as amended at 41 FR 51787, Nov. 24, 1976; 55 FR 38316, Sept. 18, 1990]

§ 265.2 Applicability.

The regulations in this part establish rules with respect to the parking and operation of motor vehicles and other activities and conduct on the site. These regulations are intended to supplement the rules and regulations regarding conduct in Part O of Subtitle A of this title and in other officially issued orders and regulations of the Department of Commerce and the National Institute of Standards & Technology

[39 FR 41170, Nov. 25, 1974, as amended at 55 FR 38316, Sept. 18, 1990]

§ 265.3 Compliance with directions.

No person shall fail or refuse to comply with any lawful order or direction of a uniformed guard in connection with the control or regulation of traffic and parking or other conduct on the site.

§ 265.4 Making or giving of false reports.

No person shall knowingly give any false or fictitious report or information to any authorized person investigating an accident or apparent violation of law or these regulations. Nothing in this section shall affect the applicability of 18 U.S.C. 1001 regarding false, fictitious or fraudulent statements or entries.

§ 265.5 Laws of Maryland and Colorado applicable.

Unless otherwise specifically provided herein, the laws of the State of Maryland and of the State of Colorado shall be applicable to the site located within those respective States. The applicability of State laws shall not, however, affect or abrogate any other Federal law or regulation applicable under the circumstances.

Subpart B—Traffic and Vehicular Regulations

§ 265.11 Inspection of license and registration.

No person may operate any motor vehicle on the site unless he holds a current operator's license, nor may he, if operating a motor vehicle on the site, refuse to exhibit for inspection, upon request of a uniformed guard, his operator's license or proof of registration of the vehicle under his control at time of operation.

§ 265.12 Speeding or reckless driving.

(a) No person shall drive a motor vehicle on the site at a speed greater than or in a manner other than is reasonable and prudent for the particular location, given the conditions of traffic, weather, and road surface and having regard to the actual and potential hazards existing.

(b) Except when a special hazard exists that requires lower speed for compliance with paragraph (a) of this section, the speed limit on the site is 25 m.p.h., unless another speed limit has been duly posted, and no person shall drive a motor vehicle on the site in excess of the speed limit.

§ 265.13 Emergency vehicles.

No person shall fail or refuse to yield the right-of-way to an emergency vehicle when operating with siren or flashing lights.

§ 265.14 Signs.

Every driver shall comply with all posted traffic and parking signs.

§ 265.15 Right-of-way in crosswalks.

No person shall fail or refuse to yield the right-of-way to a pedestrian or bicyclist crossing a street in a marked crosswalk.

§ 265.16 Parking.

No person, unless otherwise authorized by a posted traffic sign or directed by a uniformed guard, shall stand or park a motor vehicle:

(a) On a sidewalk;

(b) Within an intersection or within a crosswalk;

(c) Within 15 feet of a fire hydrant, 5 feet of a driveway or 30 feet of a stop sign or traffic control device;

(d) At any place which would result in the vehicle being double parked;

(e) At curbs painted yellow;

(f) In a direction facing on-coming traffic;

(g) In a manner which would obstruct traffic;

(h) In a parking space marked as not intended for his use;

(i) Where directed not to do so by a uniformed guard;

(j) Except in an area specifically designated for parking or standing;

(k) Except within a single space marked for such purposes, when parking or standing in an area with marked spaces;

(l) At any place in violation of any posted sign; or

(m) In excess of 24 hours, unless permission has been granted by the Physical Security office.

§ 265.17 Parking permits.

No person, except visitors, shall park a motor vehicle on the site without having a valid parking permit displayed on such motor vehicle in compliance with instructions of the issuing

authority. Such permits may be revoked by the issuing authority for violation of any of the provisions of this part.

§ 265.18 Prohibited servicing of vehicles.

No person shall make nonemergency repairs on privately owned vehicles on the site.

§ 265.19 Unattended vehicles.

No person shall leave a motor vehicle unattended on the site with the engine running or a key in the ignition switch or the vehicle not effectively braked.

§ 265.20 Towing of improperly parked vehicles.

Any motor vehicle that is parked in violation of these regulations may be towed away or otherwise moved if a determination is made by a uniformed guard that it is a nuisance or hazard. A reasonable amount for the moving service and for the storage of the vehicle, if any, may be charged, and the vehicle is subject to a lien for that charge.

§ 265.21 Improper use of roads as thoroughfares.

Except as otherwise provided herein, no person shall drive a motor vehicle or bicycle onto the site for the sole purpose of using the roads of the site as a thoroughfare between roads bordering the site. This section shall not apply to bicyclists using officially approved bike paths on the site.

§ 265.22 Bicycle traffic.

No person shall ride a bicycle other than in a manner exercising due caution for pedestrian and other traffic. No person shall ride a bicycle on sidewalks or inside any building, nor shall any person park a bicycle on sidewalks or inside any building nor in a roadway or parking lot, provided, however, that these parking restrictions shall not apply to bicycles parked at bicycle racks located in these areas.

Subpart C—Buildings and Grounds

§ 265.31 Closing the site.

As determined by the Director (Director, NIST Boulder Laboratories, for sites in Colorado), the site may be closed to the public in emergency situations and at such other times as may be necessary for the orderly conduct of the Government's business. At such times no person shall enter the site except authorized individuals, who may be required to sign a register and display identification when requested by a uniformed guard.

[39 FR 41170, Nov. 25, 1974, as amended at 56 FR 66969, Dec. 27, 1991]

§ 265.32 Trespassing.

No person shall come onto the site other than in pursuance of official government business or other properly authorized activities.

§ 265.33 Preservation of property.

No person shall, without authorization, willfully destroy, damage, or deface any building, sign, equipment, marker, or structure, tree, flower, lawn, or other public property on the site.

§ 265.34 Conformity with posted signs.

No person shall fail or refuse to comply with officially posted signs of a prohibitory nature or with directions of a uniformed guard.

§ 265.35 Nuisances.

(a) No person shall willfully disrupt the conduct of official business on the site, or engage in disorderly conduct; nor shall any person unreasonably obstruct the usual use of entrances, foyers, lobbies, corridors, offices, elevators, stairways, parking lots, sidewalks, or roads.

(b) No person shall litter or dispose of rubbish except in a receptacle provided for that purpose; nor shall any person throw articles of any kind from a building or from a motor vehicle or bicycle.

§ 265.36 Intoxicating beverages.

Except as expressly authorized by the Director, the consumption or use on the site of intoxicating beverages is prohibited.

§ 265.37 Narcotics and other drugs.

The possession, sale, consumption, or use on the site of narcotic or other

drugs illegal under the laws of the State in which the particular site is situated is prohibited. The provisions of this section are not intended to preclude the applicability of any State or local laws and regulations with respect to the possession, sale, consumption, or use of narcotic or other drugs.

§265.38 Intoxication or other impairment of function.

No person shall enter or remain on the site while noticeably impaired by the use of intoxicating beverages or narcotics or other drugs, and any such person found on the site in such a state of impairment may be removed from the site.

§265.39 Weapons and explosives.

Except in connection with the conduct of official business on the site, no person other than uniformed guards specifically authorized, or other Federal, State, or local law enforcement officials so authorized, shall carry, transport, or otherwise possess on the site, firearms whether loaded or not, other dangerous or deadly weapons or materials, or explosives, either openly or concealed, without the written permission of the Director or his designee.

§265.40 Nondiscrimination.

No person shall discriminate against any other person because of race, creed, color, sex, or national origin, in furnishing, or by refusing to furnish to such person the use of any facility of a public nature, including all services, privileges, accommodations, and activities provided thereby on the site.

§265.41 Gambling.

No person shall participate on the site in games for money or other property, or in the operation of gambling devices, the conduct of lotteries or pools, or in the selling or purchasing of numbers tickets, or the taking or placing of bets.

§265.42 Photography for advertising or commercial purposes; advertising and soliciting.

(a) Except as otherwise provided herein or where security regulations would preclude, photographs may be taken in entrances, lobbies, foyers, corridors, and auditoriums without prior approval. Photography for advertising and commercial purposes may be conducted only with the written permission of the Chief, Public Affairs Division of the National Institute of Standards and Technology (Public Affairs Officer for Boulder for sites in Colorado,) provided, however, that this shall not apply to photography for purposes of civic promotion.

(b) Commercial advertisements and other material which are not directly pertinent or applicable to NIST employees but which nevertheless may be of interest or benefit to them may, with the approval of the Director of Administration (Executive Office, Boulder, for sites in Colorado), be placed in an appropriate location and made available to employees who visit that area. Except with approval as provided herein, no person shall distribute commercial advertising literature or engage in commercial soliciting on the site.

[39 FR 41170, Nov. 25, 1974, as amended at 55 FR 38316, Sept. 18, 1990; 56 FR 66969, Dec. 27, 1991]

§265.43 Pets and other animals.

Except in connection with the conduct of official business on the site or with the approval of the Associate Director for Administration (Executive Officer, IBS/Boulder, for sites in Colorado), no person shall bring upon the site any cat, dog, or other animal, provided, however, that blind persons may have the use of seeing eye dogs.

Subpart D—Penalties

§265.51 Penalties—other laws.

Except with respect to the laws of the State of Maryland and the State of Colorado assimilated by §265.5 or otherwise, whoever shall be found guilty of violating these regulations is subject to a fine of not more than $50 or imprisonment of not more than 30 days, or both (40 U.S.C. 318c). Except as expressly provided in this part, nothing contained in these regulations shall be construed to abrogate any other Federal laws or regulations, or any State and local laws and regulations applicable to the area in which the site is situated.

SUBCHAPTER G—INVENTION EVALUATION PROCEDURES [RESERVED]

SUBCHAPTERS H–I [RESERVED]
SUBCHAPTER J—ACCREDITATION AND ASSESSMENT PROGRAMS

PART 280—FASTENER QUALITY

Subpart A—General

Subpart B—Laboratory Accreditation

Subpart C—NIST Fastener Laboratory Accreditation Procedures

Subpart D—NIST Approval of Private Accreditation Programs

Subpart E—Recognition of Foreign Laboratories

Subpart F—Requirements for Fastener Laboratory Accreditation Bodies

Subpart G—Enforcement

AUTHORITY: 15 U.S.C. 5401 *et seq.*; Pub. L. 105–234, 112 Stat. 1536.

SOURCE: 61 FR 50558, Sept. 26, 1996, unless otherwise noted.

Subpart A—General

§ 280.1 Purpose/description of rule.

The Fastener Quality Act (the Act) (Pub.L. 101–592, as amended by Pub. L. 104–113) is intended to protect the public safety, to deter the introduction of nonconforming fasteners into commerce, to improve the ability to trace fasteners covered by the Act, and generate greater assurance that fasteners meet stated specifications. The Act:

(a) Requires that certain fasteners which are sold in commerce conform to

the specifications to which they are represented to be manufactured,

(b) Provides for accreditation of laboratories engaged in fastener testing; and

(c) Requires inspection, testing and certification, in accordance with standardized methods, of fasteners covered by the Act.

(d) *Delegations of authority*. The Secretary of Commerce has delegated authority to the Director, National Institute of Standards and Technology to promulgate regulations in this part under sections 5 through 8 of the Fastener Quality Act (15 U.S.C. 5404–5407). In addition, the Secretary of Commerce has delegated concurrent authority to the Under Secretary for Export Administration to amend the regulations issued under sections 5 through 7 of the Act, regarding enforcement. The Secretary of Commerce has also delegated concurrent authority to amend the regulations issued under section 8 of the Act, regarding recordal of insignias, to the Assistant Secretary and Commissioner of Patents and Trademarks.

[61 FR 50558, Sept. 26, 1996, as amended at 63 FR 18271, Apr. 14, 1998]

§ 280.2 Definitions.

Unless the context requires otherwise or unless specifically stated the terms in this part have the meanings prescribed in the statute. In addition the following definitions apply.

Accreditation for purposes of the Act and this part means accreditation of a testing laboratory or the registration of a fastener manufacturing facility employing a quality assurance system (a Facility).

Accreditation body refers to the National Voluntary Laboratory Accreditation Program and those private entities currently approved by NIST under subpart D of this part and those foreign governments or organizations currently recognized by NIST under subpart E of this part.

Accreditation criteria means a set of requirements used by an accreditation body which a laboratory must meet to be accredited.

Accredited registrar means a registrar, as defined in this part, that is accredited by a recognized accreditor and appears on the Registrars List described in section 280.810(b).

Accreditor means a Registrar accreditation body that meets the requirements of subpart K of this part.

The Act means the Fastener Quality Act (Pub.L. 101–592, as amended by Pub.L. 104–113).

Alter means to alter by through hardening; by electroplating of fasteners; or by machining.

Alteror means a person who owns a fastener and causes it to be altered.

Approved signatory is an individual employed by a laboratory accredited under the Act and these regulations who is recognized by an accreditation body as competent to sign accredited laboratory test reports.

Authorized representative means an employee of an organization who is authorized by that organization to speak on its behalf for purposes of the Act and this part.

Bureau of Export Administration or (*BXA*) means the Bureau of Export Administration of the United States Department of Commerce, including the Office of Export Enforcement.

Certificate of accreditation is a document issued by an accreditation body to a laboratory that has met the criteria and conditions of accreditation. The certificate, together with the assigned code number, and scope of accreditation issued by the accreditation body may be used as proof of accredited status.

Certified copy (of a laboratory testing report) means a complete and accurate copy of the original laboratory testing report, which contains a statement describing it as an accurate and complete copy of the original and which is signed by an authorized representative of the accredited laboratory issuing the report or, in the case of metal chemistry testing reports, an authorized representative of the metal manufacturer.

Commingling means the mixing of fasteners from different lots in the same container.

Commissioner means the Commissioner of Patents and Trademarks.

Consensus standards organization means the American Society for Testing and Materials (ASTM), American National Standards Institute (ANSI),

American Society of Mechanical Engineers (ASME), Society of Automotive Engineers (SAE), or any other consensus standards setting organization (domestic or foreign) publicly identified by NIST as having comparable knowledge, expertise, and concern for the health and safety in the field for which such organization purports to set standards.

Container means any package of fasteners traded in commerce.

Date of manufacture means that date upon which the initial conversion of material into a fastener takes place.

Director means the Director of the National Institute of Standards and Technology (NIST).

Facility means a fastener manufacturing facility, or a facility performing subcontracted processes for a fastener manufacturing facility, implementing a fastener quality assurance system as defined in this part.

Fastener means any screw, nut, bolt or stud, washer or other item included within the definition for fastener contained in section 3(5) of the Fastener Quality Act. The term ''fastener'' does not include a screw, nut, bolt, or stud:

(1) That is produced and marked as ASTM A307 Grade A;

(2) That is produced in accordance with ASTM F432; or

(3) That is held out as being produced to other than the provisions of standards and specifications published by a consensus standards organization, or a government agency.

A screw, nut, bolt, stud or washer held out as being produced according to requirements of a document other than a document published by a consensus standards organization is a fastener within the meaning of the Act and this part if that document incorporates or references (directly or indirectly) standards and specifications published by a consensus standards organization or government agency for purposes of delineating performance or materials characteristics of the fastener.

Fastener insignia register means the register established at the U.S. Patent and Trademark Office for the recordal of fastener insignia to identify the manufacturer or private label distributor.

Fastener Quality Assurance System (QAS)—(1) *Fastener Quality Assurance System (QAS)* means a fastener manufacturing system that has as a stated goal the prevention of defects through continuous improvement, and which seeks to attain that goal by incorporating:

(i) Advanced quality planning;

(ii) Monitoring and control of the manufacturing process;

(iii) Process inspection embodied in a comprehensive and written control plan for product/process characteristics, process controls (including statistical process control), tests, and measurement systems that will occur during mass production; and

(iv) The creation, maintenance, and retention of electronic, photographic, or paper records, available for inspection during the periods required by section 10 of the Act and § 280.7 of this part, regarding the inspections, tests, and measurements required by or performed pursuant to the control plan.

(2) A Fastener Quality Assurance System contains the following elements at a minimum:

(i) A documented quality management system that satisfies the requirements of ISO–9001 ''Quality Systems—Model for quality assurance in design, development, production, installation and servicing,'' ISO–9002 ''Quality Systems—Model for quality assurance in production, installation and servicing,'' or other quality system standards that incorporate ISO–9001 or ISO–9002 (e.g. QS–9000, AS–9000, etc.);

(ii) A requirement that raw material certification supplied to the fastener manufacturer shall be traceable to that of a mill heat of material that has been tested by a laboratory on the Accredited Laboratory List;

(iii) A requirement that subcontracted processes, including plating and heat treating, are controlled by the manufacturer, to avoid product lot contamination, and that finished lots of fasteners shall be traceable to subcontracted processes performed by a registered Facility on the Facilities List described in § 280.810 or tested by a Laboratory on the Laboratories List described in § 280.101;

(iv) A requirement that the fastener manufacturer fully document fastener

sampling and inspection points and an in-process control plan that emphasizes defect prevention, relates frequency of inspection, corrective action for nonconforming characteristics, and sampling frequency and sample size; a requirement that the control plan be made available to the customer upon request and shall identify those standards and specifications upon which the plan is based; and

(v) A requirement that the in-process control plan include those characteristics specified by the QAS standard, characteristics specifically indicated by applicable fastener standards and specifications, and those characteristics as designated by the end user for evaluating product functionality.

Fastener set means a collection of small quantities of products, including fasteners, of varying sizes, collected together and sold as a package.

Grade or property class identification marking means any symbol appearing on a fastener purporting to indicate that the fastener's base material, strength properties, or performance capabilities conform to a specific standard of a consensus standards organization or government agency. A raw material mark is not considered as a grade identification mark for purposes of these regulations unless this mark is required by the fastener standards and specifications to identify specific conformance.

Importer means a person located within the United States who contracts for the initial purchase of fasteners manufactured outside the United States for resale or such person's use within the United States.

Laboratory accreditation is the formal recognition that a testing laboratory is competent to carry out specific test(s) or specific type(s) of tests.

Laboratory accreditation body means a legal or administrative entity that accredits laboratories.

Laboratory assessment means the onsite examination of a testing laboratory to evaluate its compliance with specified criteria.

Laboratory test report means a report prepared by an accredited laboratory in accord with § 280.6.

Lot means a quantity of fasteners of one part number fabricated by the same production process from the same coil or heat number of metal as provided by the metal manufacturer and submitted for inspection and testing at one time.

Lot number means a number assigned by a manufacturer to the lot.

Lot-specific identification information means information applicable to a fastener consisting of, at a minimum:

(1) The part number (or a part description if there is no applicable part number),

(2) The identity of the manufacturer, and

(3) The lot number.

Lot traceability means the recording and maintenance of lot-specific identification information sufficient to trace fasteners from a single lot throughout:

(1) The manufacturer's fabrication or alteration process,

(2) All inspection and testing operations, and

(3) The subsequent chain of distribution in commerce.

Manufacturer means a person who fabricates fasteners, who significantly alters fasteners, or who alters any item so that it becomes a fastener.

NIST means the National Institute of Standards and Technology, U.S. Department of Commerce.

NVLAP means the National Voluntary Laboratory Accreditation Program operated by the National Institute of Standards and Technology.

Original laboratory testing report means: (1) In general, a laboratory testing report which is originally signed by an approved signatory or is a copy thereof, certified by the laboratory that conducted the test; or

(2) For purposes of the alternative procedures for chemical characteristics described in section 5(d) of the Act and § 280.15 of this part only, a laboratory testing report which is originally signed by an approved signatory or is a copy thereof, certified by the laboratory that conducted the test or by the metal manufacturer.

Person means any individual, partnership, limited partnership or corporate entity and/or a representative, agent or designee.

Private label distributor means a person who contracts with a manufacturer for the fabrication of fasteners bearing

the distributor's distinguishing insignia.

Product includes any type or category of manufactured goods, constructions, installations, or natural or processed materials.

Proficiency testing means the determination of laboratory testing performance by means of comparing and evaluating tests on the same or similar items or materials in accordance with predetermined conditions.

Recognized accreditor means an accreditor, as defined in this part, that is recognized by NIST and appears on the Accreditors List described in § 280.810(a).

Registered facility means a facility, as defined in this part, that is registered by an accredited registrar and appears on the Facilities List described in § 280.810(c).

Registrar means a quality systems Registrar that meets the requirements of subpart L of this part.

Registration means evaluation and certification of a manufacturing facility as competent to carry out and conforming to the applicable requirements of a Fastener Quality Assurance System when such evaluation and certification is performed by a Registrar as defined in this part.

Scope of accreditation is a document issued by an accreditation body to an accredited laboratory which lists the test methods, standards or specifications for which the laboratory is accredited.

Secretary means the Secretary of Commerce.

Significantly alter means to alter or take any other action which could weaken or otherwise materially affect the performance or capabilities of the fastener as it was originally manufactured, grade or property class marked, tested, or represented. The term does not include the application of adhesives or sealants, locking elements, provisions for lock wires, coatings and platings of parts having a minimum specified Rockwell C hardness of less than 32, or cutting off of fasteners. The cutting of finished threaded rods, bars or studs to produce individual smaller length threaded studs for resale is not a significant alteration. However, cut threaded studs, rods, and bars offered for sale shall be individually marked with the grade or property class identification marking appearing on or accompanying the original threaded studs, rods, and bars from which the fasteners were cut.

Standards and specifications means the provisions of a document published by a consensus standards organization, or a government agency.

Tamper-resistant system means the use of special paper or embossing stamps or other controls which discourage, prevent or minimize alteration of test reports subsequent to manufacturing, inspection and testing.

Testing laboratory is a laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products.

Through-harden means heating above the transformation temperature followed by quenching and tempering for the purpose of achieving a uniform hardness.

Traceability of measurements means a documented chain of comparisons connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and, ultimately, to a primary standard.

[61 FR 50558, Sept. 26, 1996, as amended at 63 FR 18271, Apr. 14, 1998; 63 FR 34965, June 26, 1998]

§ 280.3 Relationship to State laws.

Nothing in the Act or these regulations shall be construed to preempt any rights or causes of action that any buyer may have with respect to any seller of fasteners under the law of any State, except to the extent that the provisions of the Act or these regulations are in conflict with such State law.

§ 280.4 Commingling of fasteners.

(a) No manufacturer, importer, or private label distributor may commingle fasteners of the same type, grade, and dimension from different lots in the same container; except that such manufacturer, importer, or private label distributor may commingle fasteners of the same type, grade, and dimension from not more than two tested and certified lots in the same

container during repackaging and plating operations: Provided, that any container which contains the fasteners from two lots shall be conspicuously marked with the lot identification numbers of both lots.

(b) Fastener distributors, and persons who purchase fasteners for sale at wholesale or retail, may commingle fasteners of the same type, grade, and dimension from different lots in the same container.

§280.5 Certification of fasteners.

(a) No fastener shall be offered for sale or sold in commerce unless it is part of a lot which has been inspected, tested, and certified in accordance with Section 5 of the Act and this part, and found to conform to the standards and specifications to which the manufacturer represents it has been manufactured.

(b)(1) The requirements of paragraph (a) of this section shall not apply to fasteners which are part of a lot of 50 fasteners or less if within 10 working days after delivery of such fasteners, or as soon as practicable thereafter—

(i) Inspection, testing, and certification as provided in subsections 5 (b), (c), and (d) of the Act and this part is carried out; and

(ii) Written notice detailing the results of such inspection, testing, and certification is sent:

(A) To all purchasers of such fasteners, except retail sellers and retail consumers, and

(B) To any retail seller or retail consumer who, prior to delivery, requests such written notice.

(2) If a fastener is sold under paragraph (b) of this section, each purchaser of such fastener, except for retail sellers and retail consumers unless such retail sellers and retail consumers request such notice in advance, shall be provided, contemporaneously with each sale and delivery, written notice stating that such fastener has not yet been inspected, tested, and certified as required by the Act and this part.

(c) Each manufacturer, importer, private label distributor, or alteror who significantly alters any fastener shall keep on file and make available for inspection in accordance with the recordkeeping requirements of §280.7 an original laboratory testing report described in section 5(c) of the Act and §280.6 of this part and a manufacturer's certificate of conformance for each lot of fasteners subject to the Act and this part which that manufacturer, importer, private label distributor, or alteror who significantly alters any fastener offers for sale or sells in commerce. Such certificate shall, as a minimum, include: Fastener description information contained in §280.6(a)(4) of this part; the date of issue and serial number of the laboratory testing report; and a statement certifying that the fasteners have been manufactured according to the requirements of the applicable standards and specifications and found to conform with its requirements. The requirements of this paragraph shall not apply to an alteror who significantly alters fasteners and who delivers to the purchaser the written statement provided for by §280.11(a)(3) of this part.

§280.6 Laboratory test reports.

(a) When performing tests for which they are accredited under this part, each laboratory accredited under subparts C, D, or E of this part and currently listed in the Accredited Laboratory List shall issue test reports of its work which accurately, clearly, and unambiguously present the test conditions, test set-up, test results, and all information required by this section. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a tamper resistant system, and contain the following information:

(1) Name and address of the laboratory;

(2) Unique identification of the test report including date of issue and serial number, or other appropriate means;

(3) Name and address of client;

(4) Fastener description, including:

(i) Manufacturer (name and address);

(ii) Product family (screw, nut, bolt, washer, or stud), drive and/or head configurations as applicable;

(iii) Date of manufacture;

(iv) Head markings (describe or draw manufacturer's recorded insignia and grade identification or property class symbols);

(v) Nominal dimensions (diameter; length of bolt, screw or stud; thickness of load indicating washer); thread form and class of fit;

(vi) Product standards and specifications related to the laboratory in writing by the manufacturer, importer or distributor;

(vii) Lot number;

(viii) Specification and grade of material;

(ix) Coating material and standard and specification as applicable;

(5) Sampling information:

(i) Standards and specifications or reference for sampling scheme;

(ii) Final manufacturing lot size;

(6) Test results:

(i) Test results for each sample;

(ii) All deviations from the test method;

(iii) All other items required on test reports according to the test method;

(iv) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory and accreditation information listed in paragraph (a)(10) of this section.

(v) A statement that the samples tested either *conform* or *do not conform* to the fastener standards and specifications and identification of any nonconformance, except as provided for in §§ 280.13 and 280.14;

(7) A statement that the report must not be reproduced except in full;

(8) A statement to the effect that the test report relates only to the item(s) tested;

(9) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(10) The name of the body which accredited the laboratory for the specific tests performed which are the subject of the report, and code number assigned to the laboratory by the accreditation body, and the expiration of accreditation.

(b) When performing tests for which they are registered under this part, each facility registered under subpart I or J of this part and currently listed in the Facilities List shall issue test reports of its work which accurately, clearly, and unambiguously present test results, and all information required by this section. In addition, the facilities shall attach reports of chemical characteristics and any report of the tests conducted in a laboratory under the accredited laboratories list. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a temper resistant system, and contain the following information:

(1) Name and address of the facility;

(2) Unique identification of the test report, including date of issue and serial number, or other appropriate means including references to control plan identification;

(3) Name and address of client, if applicable;

(4) Fastener description, including:

(i) Manufacturer (name and address);

(ii) Product family (screw, nut, bolt, washer, or stud), drive and/or head configurations as applicable;

(iii) Date of manufacture;

(iv) Head markings (describe or draw manufacturer's recorded insignia and grade identification or property class symbols);

(v) Nominal dimensions (diameter; length of bolt, screw or stud; thickness of load bearing washer); thread form and class of fit;

(vi) Product standards and specifications related to the facility in writing by the manufacturer, importer or distributor;

(vii) Lot number;

(viii) Specification and grade of material;

(ix) Coating material and standard and specification as applicable;

(5) Sampling information:

(i) Standards and specifications or reference for sampling scheme;

(ii) Final manufacturing lot size;

(iii) Identification of control plan governing production of the lot to which the test report is applicable;

(6) Test results:

(i) Test results of actual tests required by applicable fastener standards and specifications, and characteristics designated by the end user;

(ii) All deviations from the test method;

(iii) All other items required on test reports according to the applicable fastener standards and specifications, and

characteristics designated by the end user;

(iv) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory/facility and accreditation/registration information listed in paragraph (b)(9) of this section.

(v) Where all processes under the applicable QAS were found to be in accordance with the inspections, tests and measurements required by the standards and specifications and the QAS and characteristics designated by the end user, a statement that the samples tested conform to the applicable fastener standards and specifications;

(vi) Where any process under the applicable QAS was found not to be in accordance with the inspections, tests, or measurements required by such QAS, a statement that the samples tested do not conform to the applicable fastener standards and specifications and identification of any nonconformance;

(7) A statement that the report must not be reproduced except in full;

(8) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(9) The name of the registrar which registered the facility, and code number assigned to the facility by the registrar, and the expiration of registration.

(c) For alternative chemical tests carried out under §280.15 of this part, each laboratory accredited under subparts C, D, or E of this part and currently listed in the Accredited Laboratory List shall provide to the fastener manufacturer, either directly or through the metal manufacturer, a written inspection and testing report containing all required information. All reports must be in English or be translated into English, must be signed by an approved signatory, must be protected by a tamper resistant system, and contain the following information:

(1) Name and address of the laboratory;

(2) Unique identification of the test report including date of issue and serial number or other appropriate means;

(3) Name and address of client;

(4) Coil or heat number of metal being tested;

(5) Test results:

(i) Actual tests required by the standards and specifications;

(ii) Test results for such coil or heat number chemical characteristics;

(iii) All deviations from the test method;

(iv) All other items required on test reports according to the test method;

(v) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory and accreditation information listed in paragraph (c)(9) of this section.

(vi) A statement that the samples tested either *conform* or *do not conform* to the metal standards and specifications and identification of any nonconformance;

(6) A statement that the report must not be reproduced except in full;

(7) A statement to the effect that the test report relates only to the item(s) tested;

(8) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(9) The name of the body which accredited the laboratory for the specific tests performed which are the subject of the report, and code number assigned to the laboratory by the accreditation body, and the expiration of accreditation.

(d) The laboratory shall issue corrections or additions to a test report only by a further document suitably marked, e.g., ''Supplement to test report serial number * * *.'' This document must specify which test result is in question, the content of the result, the explanation of the result, and the reason for acceptance of the result.

(e) For tests carried out by a Facility registered pursuant to subpart I or J of this part, the Facility shall maintain laboratory test reports in the forms of electronic, photographic, or paper records, available for inspection during the periods required by section 10 of

the Act and § 280.7 of this part, regarding the inspections, tests, and measurements required or performed pursuant to the QAS control plan.

[63 FR 18272, Apr. 14, 1998; 63 FR 34965, June 26, 1998]

§ 280.7 Recordkeeping requirements.

(a) Each laboratory accredited under subparts C, D, or E or § 280.104 of this part shall retain for 5 years after the performance of a test all records pertaining to that test concerning the inspection and testing, and certification, of fasteners under the Act and this part. The final test report or the test records maintained by the laboratory shall contain sufficient information to permit the test to be repeated at a later time if a retest is necessary. The laboratory shall maintain the test report and a record of all original observations, calculations, and derived data. The records shall include the identity of personnel performing the testing. Procedures for storage and retrieval of records must be documented and maintained in the laboratory's quality manual.

(b) Manufacturers, importers, private label distributors, and persons who significantly alter fasteners shall retain for 5 years after the performance of a test all records pertaining to that test concerning the inspection and testing, and certification, of fasteners under the Act and these regulations.

(c) Original records required. Persons required to keep records under this part must maintain the original records in the form in which that person receives or creates them unless that person meets all of the conditions of paragraph (d) of this section relating to reproduction of records. Original laboratory test reports described in §§ 280.5, 280.6, 280.13 and 280.15(b) of this part must be kept.

(d) Reproduction of original records. A person required to keep records under this part may maintain reproductions of documents other than laboratory test reports instead of the original records using any photographic, photostatic, miniature photographic, micrographic, automated archival storage, or other process that completely, accurately, legibly and durably reproduces the original records (whether on paper, microfilm, or through electronic digital storage techniques). The process must meet all of the requirements of paragraphs (d)(1) through (d)(9) of this section.

(1) The system must be capable of reproducing all records on paper.

(2) The system must record and be able to reproduce all marks, information, and other characteristics of the original record, including both obverse and reverse sides of paper documents in legible form.

(3) When displayed on a viewer, monitor, or reproduced on paper, the records must exhibit a high degree of legibility and readability. (For purposes of this section, legible and legibility mean the quality of a letter or numeral that enable the observer to identify it positively and quickly to the exclusion of all other letters or numerals. Readable and readability mean the quality of a group of letters or numerals being recognized as complete words or numbers.)

(4) The system must preserve the initial image (including both obverse and reverse sides of paper documents) and record all changes, who made them and when they were made. This information must be stored in such a manner that none of it may be altered once it is initially recorded.

(5) The regulated person must establish written procedures to identify the individuals who are responsible for the operation, use and maintenance of the system.

(6) The regulated person must establish written procedures for inspection and quality assurance of records in the system and document the implementation of those procedures.

(7) The system must be complete and contain all records required to be kept by this part or the regulated person must provide a method for correlating, identifying and locating records relating to the same transaction(s) that are kept in other record keeping systems.

(8) The regulated person must keep a record of where, when, by whom, and on what equipment the records and other information were entered into the system.

(9) Upon request by the Bureau of Export Administration or NIST, the regulated person must furnish, at the examination site, the records, the equipment and, if necessary, knowledgeable personnel for locating, reading, and reproducing any record in the system.

(e) Destruction or disposal of records. If the Bureau of Export Administration, NIST or any other government agency makes a formal or informal request for any record or records, such record or records may not be destroyed or disposed of without the written authorization of the agency concerned. This prohibition applies even if such records have been retained for a period of time exceeding that required by paragraphs (a) or (b) of this section.

(f) All persons required to keep records by this part must furnish those records when requested to do so by an employee of the Bureau of Export Administration or NIST.

[61 FR 50558, Sept. 26, 1996, as amended at 63 FR 18274, Apr. 14, 1998]

§ 280.8 Ownership of laboratories by manufacturers.

(a) If the Director finds that, as to a specific type of fastener, and as to a specific type of inspection or testing, a ban on manufacturer ownership or affiliation with a laboratory performing tests under the Act and these regulations would increase the protection of health and safety of the public or industrial workers, the Director may impose such a ban.

(b) Before imposing a ban under paragraph (a) of this section, the Director shall provide advance notice and the opportunity for public comment.

§ 280.9 Subcontracting of testing.

(a) Whenever a laboratory accredited under subparts C, D, or E of this part issues a test report under the Act and this part, it is implied that the report reflects work performed, and results obtained, by the personnel, equipment, and procedures of that laboratory. However, in some cases a laboratory may require the use of another facility due to equipment failure, need for specialized equipment, work overload, or to perform tests outside the laboratory's own scope of accreditation.

(b) Whenever a laboratory accredited under subparts C, D, or E of this part subcontracts to another laboratory for the performance of any test or portion of a test it must:

(1) Place the work with another laboratory accredited under either subpart C, D, or E of this part;

(2) Inform the client, before the fact, that subcontracting will be necessary; and

(3) Clearly identify in its records, and in the report to the client, specifically which test method(s) or portions of a test method(s) were performed by the accredited laboratory and which were performed by the subcontractor.

§ 280.10 Sampling.

(a) For tests conducted either in a laboratory on the Accredited Laboratory List or in a Registered Facility, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which provides for the size, selection or integrity of the sample to be inspected and tested, the sample shall be determined in accordance with that standard or specification.

(b) For tests conducted in a laboratory on the Accredited Laboratory List, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which does not provide for the size, selection or integrity of the sample to be inspected and tested, the sample shall be determined in accordance with the sampling plan provided by ASME/ANSI B18.18.2M, Inspection and Quality Assurance For High-Volume Machine Assembly Fasteners; ASME/ANSI B18.18.3M, Inspection and Quality Assurance for Special Purpose Fasteners; or ASME/ANSI B18.18.4M, Inspection and Quality Assurance for Highly Specialized Engineering Applications—Fasteners.

(c) For tests conducted in a Registered Facility, and not in a laboratory on the Accredited Laboratory List, if a manufacturer represents that the fasteners in a particular sample have been manufactured to a standard or specification which does not provide for the size, selection or integrity of the sample to be inspected and tested, the sample for inspections and tests by

the Facility shall be determined by the sampling plan provided by its Fastener Quality Assurance System or by standards and specifications intended for use with a Fastener Quality Assurance System, as appropriate. Or, a manufacturer operating a Registered Facility may elect to conduct inspections and tests upon all of the fasteners within a specified lot, provided that this election is documented in the control plan of its Fastener Quality Assurance System.

[63 FR 18274, Apr. 14, 1998]

§ 280.11 Significant alterations of fasteners.

(a) Any alteror who significantly alters a fastener so that it no longer conforms to the description in the relevant test report issued under section 5(c) of the Act or this part, and who thereafter offers for sale or sells such significantly altered fastener, shall:

(1) Assign a new lot number;

(2) Apply his or her registered insignia to the significantly altered fastener if the standards and specifications to which the fastener was originally manufactured required the fastener to bear a raised or depressed insignia identifying its manufacturer or private label distributor; and

(3) Be treated as a manufacturer for the purposes of the Act and this part, and shall cause the fastener to be inspected and tested as required by section 5 of the Act and by this part unless the significantly altered fastener is delivered to a purchaser accompanied by a written statement noting the original lot number and the new lot number assigned by the alteror, disclosing the subsequent alteration, and warning that such alteration may affect the dimensional or physical characteristics of the fastener.

(b) If the significant alteration is only electroplating of fasteners having a minimum specified Rockwell C hardness of 32 or above, the requirements set forth in paragraphs (a)(2) and (a)(3) of this section shall not apply, but the alterer shall assign a new lot number as set forth in paragraph (a)(1) of this section and shall test the electroplated fasteners as required by the plating standards and specifications.

(c) Any person who knowingly sells a significantly altered fastener as described in paragraph (a) of this section, and who did not alter such fastener, shall provide to the purchaser a copy of the statement required by paragraph (a)(3) of this section; unless the significant alteration is only electroplating of the fastener, as described in paragraph (b) of this section.

(d) If the alteration is not a significant alteration, the requirements set forth in paragraph (a) of this section shall not apply, and the only testing requirements which apply are those required by the standards and specifications to which the alteration is performed. If the alteration involves cutting of threaded studs, rods, or bars into studs, these cut fasteners must be marked with the grade or property class identification marking appearing on the original threaded studs, rods, and bars.

[61 FR 50558, Sept. 26, 1996, as amended at 63 FR 18274, Apr. 14, 1998]

§ 280.12 Applicability.

(a) The requirements of the Fastener Quality Act and this part shall be applicable only to fasteners manufactured on or after June 1, 1999.

(b) Metal manufactured prior to June 1, 1999, may not be used to manufacture fasteners subject to the Act and this part unless the metal has been tested for chemistry pursuant to §280.15 of this part by a laboratory accredited under the Act and this part and the chemical characteristics of the metal conform to those required by the standards and specifications.

(c) Nothing in the Act and this part prohibits selling finished fasteners manufactured prior to June 1, 1999, or representing that such fasteners meet standards and specifications of a consensus standards organization or a government agency.

[63 FR 51526, Sept. 28, 1998]

§ 280.13 Imports of fasteners.

(a) Except as provided in paragraph (b) of this section, it shall be unlawful for any person to sell to an importer, and for any importer to purchase any shipment of fasteners or fastener sets manufactured outside the United

States unless such shipment to an importer is accompanied by a manufacturer's certificate of conformance, an original laboratory testing report with respect to each lot from which the fasteners are taken, and any other relevant lot identification information.

(b) The requirement that delivery of fasteners to any importer must be accompanied by an original laboratory testing report shall not apply:

(1) In the case of fasteners imported into the United States as products manufactured within a nation which is party to a congressionally approved free trade agreement with the United States that is in effect, provided that the Director has published in the FEDERAL REGISTER a certification that satisfactory arrangements have been reached by which purchasers within the United States can readily gain access to an original laboratory test report for such fasteners; or,

(2) In the case of fasteners imported into the United States as Canadian-origin products under the United States-Canada Automobile Pact for use as original equipment in the manufacture of motor vehicles.

§280.14 Option for importers and private label distributors.

(a) Notwithstanding the provisions of §280.13 of this part, delivery of a lot, or portion of a lot, of fasteners may be made by a manufacturer to an importer or private label distributor without the required original copy of the laboratory testing report if—

(1) The manufacturer provides to the importer or private label distributor a certificate which, as a minimum, includes fastener description information contained in §280.6(a)(4), and a statement by the manufacturer certifying that the fasteners have been manufactured according to the requirements of the applicable standard or specification, but have not been tested by a laboratory accredited in accordance with section 6 of the Act; and

(2) The importer or private label distributor assumes responsibility in writing for the inspection and testing of such lot or portion by a laboratory accredited in accordance with the procedures set out in this Part.

(b) If the importer or private label distributor assumes the responsibility in writing for the inspection and testing of such lot or portion, the provisions of section 5(a), (b) and (c) of the Act shall apply to the importer or private label distributor in the same manner and to the same extent as to a manufacturer; except that the importer or private label distributor shall provide to the testing laboratory the certificate described under paragraph (a)(1) of this section.

§280.15 Alternative procedure for chemical characteristics.

Notwithstanding any other provision of this regulation, a manufacturer shall be deemed to have demonstrated that the chemical characteristics of a lot conform to the standards and specifications to which the manufacturer represents such lot has been manufactured if the following requirements are met:

(a) The coil or heat number of metal from which such lot was fabricated has been inspected and tested with respect to its chemical characteristics by a laboratory accredited in accordance with the Act and these regulations;

(b) Such laboratory has provided to the manufacturer, either directly or through the metal manufacturer, a written inspection and testing report, prepared in accordance with §280.6 of this part, listing the chemical characteristics of such coil or heat number;

(c) The report described in paragraph (b) of this section indicates that the chemical characteristics of such coil or heat number conform to those required by the standards and specifications to which the manufacturer represents such lot has been manufactured; and,

(d) The manufacturer demonstrates that such lot has been fabricated from the coil or heat number of metal to which the report described in paragraphs (b) and (c) of this section relates.

§280.16 Subsequent purchaser.

(a) If a purchaser of fasteners requests the seller to mark the container of fasteners with the lot number from which such fasteners were taken, either prior to the sale or at the time of sale, the seller shall conspicuously

mark the container of fasteners with the lot number.

(b) The seller shall provide copies of any applicable laboratory testing report or certification of conformance upon request to the subsequent purchaser of fasteners taken from the lot to which such testing report or manufacturer's certificate of conformance relates.

Subpart B—Laboratory Accreditation

§ 280.100 Introduction.

The Fastener Quality Act sets out three alternatives by which a laboratory may become accredited for testing under the Act. This regulation sets out implementing procedures for each of those alternatives:

(a) Subpart C of this part contains procedures by which the National Institute of Standards and Technology's National Voluntary Laboratory Accreditation Program will accredit laboratories for the testing of fasteners under the Act;

(b) Subpart D of this part sets out procedures under which private entities may apply to NIST for approval to engage directly in the accreditation of laboratories for the testing of fasteners under the Act; and

(c) Subpart E of this part sets out conditions under which the accreditation of foreign laboratories by their governments or organizations recognized by the Director shall be deemed to satisfy the laboratory accreditation requirements for the testing of fasteners under the Act.

§ 280.101 Accredited laboratory list.

NIST shall prepare and maintain an Accredited Laboratory List of laboratories accredited under subparts C, D, and E of this part. Only laboratory test reports covering tests performed by a laboratory listed in the Accredited Laboratory List at the time the report was issued, and which are within the scope of the laboratory's accreditation, shall be deemed to meet the requirements of the Act.

§ 280.102 Procedures for inclusion in the accredited laboratory list.

(a) NVLAP, and all entities approved by NIST under subpart D of this part or recognized by NIST under subpart E of this part shall promptly notify NIST of each accreditation action taken under subparts C, D, or E of this part, respectively. Accreditation actions include initial accreditation, denials of accreditation, renewals, suspensions, terminations, revocations and changes in scope. Notifications shall be filed with: Fastener Quality Act Program Manager, Office of Standards Services, National Institute of Standards and Technology, Gaithersburg, Maryland 20899.

(b) Each notification to NIST shall include the following information, in English: The name of the laboratory accreditation body which granted the accreditation; the name and address of the laboratory affected by the accreditation action; the nature of the accreditation action; a copy of the laboratory's accreditation certificate and a scope of accreditation which states the fastener test methods for which it has been accredited; the name and telephone number of the authorized representative(s) and approved signatory(s) of the fastener testing laboratory; information concerning the physical locations of all organizational units involved in accredited fastener testing, and the specific scope of fastener testing for each organizational unit for which accreditation has been granted.

(c) NIST shall revise as appropriate the Accredited Laboratory List when notified of accreditation actions and shall take appropriate steps to make information changes promptly available to the public.

§ 280.103 Removal from the accredited laboratory list.

(a) NIST may remove from the Accredited Laboratory List any fastener testing laboratory accredited under subpart C, D or E of this part if NIST deems such action to be in the public interest. Laboratory test reports describing tests performed by a laboratory after it has been removed from the Accredited Laboratory List under this section shall not be deemed to meet the requirements of the Act.

(b) A laboratory may appeal the removal or proposed removal from the Accredited Laboratory List to the Director by submitting a statement of reasons why the laboratory should remain on the list. NIST may, at its discretion, hold in abeyance a removal action pending a final decision by the Director. The Director shall inform the laboratory in writing of the decision within sixty days following receipt of the appeal.

§ 280.104 Accreditation of certain manufacturing facilities as laboratories.

(a) Subject to the limitations contained in paragraphs (b), (c), and (d) of this section, registration of a fastener manufacturing facility employing a fastener quality assurance system shall be deemed to meet the requirements of accreditation of a laboratory for purposes of the Act and this part. The independent third-party Registrar registering such facility under this section shall comply with all procedures set forth in subparts I through L of this part. Records documenting the inspection and testing of a lot of fasteners performed by such an accredited laboratory shall be maintained by the facility in accordance with the requirements of §§ 280.6, 280.808, and 280.809 of this part.

(b) In any instance where a Facility accomplishes any in-process inspection and testing by performing laboratory tests on a sample of fasteners at any stage in the manufacturing process, those tests must be conducted by a laboratory on the Accredited Laboratory List. Such a laboratory may be located on the same premises as a fastener manufacturing facility if the laboratory is separately accredited pursuant to a provision of this part other than § 280.104(a).

(c) Any laboratory tests performed outside the Facility's in-process inspection and testing must be conducted by a laboratory on the Accredited Laboratory List.

(d) Chemical and raw material testing must be performed by a laboratory on the Accredited Laboratory List.

[63 FR 18274, Apr. 14, 1998]

Subpart C—NIST Fastener Laboratory Accreditation Procedures

§ 280.200 Introduction.

This subpart sets out the procedures and technical requirements of the NVLAP Fasteners Testing Program (''the Program'') for the accreditation of laboratories that test fasteners. Laboratories which are granted accreditation under this program for certain tests will be eligible to provide testing services and test reports required by the Fastener Quality Act for those tests. Accreditation may be granted to any laboratory (including: Commercial; manufacturers'; university; and laboratories located in foreign countries) that demonstrates competence to provide services according to the criteria specified in this subpart. It is up to the laboratory to select the areas and specific tests within each area for its proposed scope of accreditation. A laboratory may be accredited to test and/or measure fasteners in any one or more of the areas of chemical, dimensional, nondestructive, mechanical and physical, or metallography testing. Laboratories located outside of the U.S. must meet certain additional requirements including: Additional fees for travel outside the U.S. and provision of a language translator.

§ 280.201 Applicability of part 285, title 15, Code of Federal Regulations.

As permitted by section 6 of the Act, and for the purposes of that Act only, the provisions of part 285, title 15 of the Code of Federal Regulations are superseded by the procedures and requirements set forth in this Subpart. The provisions of part 285, title 15 of the Code of Federal Regulations remain in effect except as they pertain to laboratory accreditation actions required by the Act.

§ 280.202 Establishment of the Program.

(a) NVLAP shall develop the technical requirements for the Program based on expert advice.

(b) As a means of assuring effective and meaningful cooperation, input, and participation by those federal agencies that may have an interest in and may be affected by the Program, NVLAP

may communicate and consult with appropriate officials within those agencies.

(c) When NVLAP has completed the development of the technical requirements of the Program and established a schedule of fees for accreditation, NVLAP shall publish a notice in the FEDERAL REGISTER announcing the establishment of the Program.

(d) The notice will:

(1) Identify the scope of the Program;

(2) Advise how to apply for accreditation.

(e) NVLAP shall establish fees in amounts that will enable the Program to be self-sufficient. NVLAP shall revise the fees when necessary to maintain self-sufficiency.

§ 280.203 Adding to or modifying the Program.

(a) The Program may be added to, modified, or realigned based on either a written request from any person wishing to add or delete specific standards, test methods, or types of test methods or a need identified by NVLAP.

(b) NVLAP may choose to make the additions or modifications available for accreditation when:

(1) The additional standards, test methods, or types of test methods requested are directly relevant to the Program;

(2) It is feasible and practical to accredit testing laboratories for the additional standards, test methods, or types of test methods; and

(3) It is likely that laboratories will seek accreditation for the additional standards, test methods, or types of test methods.

§ 280.204 NVLAP Program Handbook.

All specific laboratory accreditation requirements and NVLAP interpretations shall be documented in a program handbook which NVLAP shall develop and maintain. The handbook shall be made available to all participating laboratories. NVLAP may prepare a NVLAP Program Handbook for the Fastener Testing Program for use by applicant and accredited laboratories. The purpose of the handbook is to provide specific technical details for fastener testing as they apply to on-site assessment, proficiency testing, test equipment and facilities, and scope of accreditation.

§ 280.205 Applying for accreditation.

(a) A laboratory may request an application for accreditation in the Program in accordance with instructions provided in notices announcing the Program's formal establishment.

(b) Upon receipt of a laboratory's application, NVLAP shall:

(1) Acknowledge receipt of the application;

(2) Request further information, if necessary;

(3) Confirm payment of fees before proceeding with the accreditation process; and

(4) Specify the next step(s) in the accreditation process.

(c) All laboratory accreditation documents must be in English or the laboratory seeking accreditation must supply an English translation of all documents at the time it files its application.

(d) Accreditation of laboratories outside the United States may require payment of additional traveling expenses for on-site assessments and proficiency testing.

§ 280.206 Assessing and evaluating a laboratory.

(a) Information used to evaluate a laboratory's compliance with the conditions for accreditation set out in § 280.214, the criteria for accreditation set out in § 280.215, and the technical requirements established will include:

(1) Application and other material submitted by the laboratory (§ 280.214(b)).

(2) On-site assessment reports;

(3) Laboratory performance on proficiency tests;

(4) Laboratory responses to identified deficiencies; and

(5) Technical evaluation.

(b) NVLAP shall arrange the assessment and evaluation of applicant laboratories in such a way as to minimize potential conflicts of interest.

(c) NVLAP shall inform each applicant laboratory of any action(s) that the laboratory must take to qualify for accreditation.

§ 280.207 Granting and renewing accreditation.

(a) NVLAP will take action to grant initial accreditation, or renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies with the specific NVLAP requirements. Accreditation shall be granted for a one year period. Before initial accreditation and every 2 years thereafter, an on-site assessment of each laboratory shall be conducted to determine compliance with the NVLAP criteria.

(b) If accreditation is granted or renewed, NVLAP shall:

(1) Provide a Certificate of Accreditation and a Scope of Accreditation to the laboratory;

(2) Provide guidance on referencing the laboratory's accredited status, and the use of the NVLAP logo by the laboratory and its clients, as needed; and

(3) Remind the laboratory that accreditation does not relieve it from complying with applicable federal, state, and local laws and regulations.

(c) NVLAP shall notify an accredited laboratory at least 30 days before its accreditation expires advising of the action(s) the laboratory must take to renew its accreditation.

§ 280.208 Denying, suspending, and revoking accreditation.

(a) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

(b) The laboratory will have 30 days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within that 30-day period.

(c) If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may, after consultation with the laboratory, suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation. If accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated.

(d) A laboratory whose accreditation has been denied, revoked, terminated, or expired, or which has withdrawn its application before being accredited, may reapply and be accredited if the laboratory:

(1) Completes the assessment and evaluation process; and

(2) Meets the conditions and criteria for accreditation that are set out in sections 280.214 and 280.215.

(e) Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test reports during the suspension period. The determination of NVLAP whether to suspend or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

§ 280.209 Voluntary termination of accreditation.

A laboratory may at any time terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so. NVLAP shall terminate the laboratory's accreditation and shall notify the laboratory stating that its accreditation has been terminated in response to its request.

§ 280.210 Change in status of laboratory.

Accreditation of a laboratory is based on specific conditions and criteria including the laboratory ownership, location, staffing, facilities, and configuration. Changes in any of these conditions or criteria could result in loss of accreditation. NVLAP must be informed if any of the conditions or criteria for accreditation are changed so that a determination can be made concerning the status of the accreditation.

§ 280.211 Authorized representative.

The laboratory shall designate an Authorized Representative to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements. Only the Authorized Representative can authorize a change in the scope or nature of the laboratory's application. This person will receive all correspondence and inquiries from NVLAP. The Authorized Representative may also be an Approved Signatory. The laboratory must provide to NVLAP the name and address of the Authorized Representative and must, within 30 days, notify NVLAP of a change of Authorized Representative.

§ 280.212 Approved signatory.

(a) The laboratory shall designate one or more staff members as Approved Signatories. Approved Signatories shall be persons with appropriate responsibility, authority and technical capability within the organization. The laboratory must maintain a list of Approved Signatories and make that list available for review during on-site assessments. The laboratory must provide to NVLAP the name(s) and address(es) of the Approved Signatory(s) and must, within 30 days, notify NVLAP of a change of Approved Signatory(s).

(b) The authorized signature of at least one Approved Signatory must appear on each test reports that is written in compliance with the Act and endorsed with the NVLAP logo. The approved signatory is responsible for the technical content of the report and is the person to be contacted by NVLAP, laboratory clients, or others in case of questions or problems with the report.

§ 280.213 Application of accreditation conditions and criteria.

To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in § 280.214, the criteria set out in § 280.215, and the guidance provided in the Program Handbook.

§ 280.214 Conditions for accreditation.

(a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(1) Be assessed and evaluated initially and on a periodic basis;

(2) Demonstrate, on request that it is able to perform the tests representative of those for which it is seeking accreditation;

(3) Pay all fees;

(4) Participate in proficiency testing as required.

(5) Be capable of performing the tests for which it is accredited according to the latest version of the test method within one year after its publication or within another time limit specified by NVLAP;

(6) Limit the representation of the scope of its accreditation to only those tests or services for which accreditation is granted;

(7) Resolve all deficiencies;

(8) Limit all its work or services for clients to those areas where competence and capacity are available;

(9) Inform its clients that the laboratory's accreditation or any of its test reports in no way constitutes or implies product certification, approval, or endorsement by NIST;

(10) Maintain records of all actions taken in response to testing complaints for 5 years, as required by § 280.7 of this part;

(11) Maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render test reports objectively and without bias is not adversely affected;

(12) Report to NVLAP within 30 days any major changes involving the location, ownership, management structure, authorized representative, approved signatories, or facilities of the laboratory; and

(13) Return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for revision or other action should it:

(i) Be requested to do so by NVLAP;

(ii) Voluntarily terminate its accredited status; or

(iii) Become unable to conform to any of these conditions, the applicable criteria of this Subpart or § 280.215, and related technical requirements.

(b) To become accredited and maintain accreditation, a laboratory shall

supply, upon request, the following information:

(1) Legal name and full address;

(2) Ownership of the laboratory;

(3) Organization chart defining relationships that are relevant to performing testing covered in the accreditation request;

(4) General description of the laboratory, including its facilities and scope of operation;

(5) Name, address, and telephone and FAX number of the authorized representative of the laboratory;

(6) Names or titles and qualifications of laboratory staff nominated to serve as approved signatories of test reports that reference NVLAP accreditation;

(7) The laboratory quality manual; and

(8) Other information as NVLAP may require.

§280.215 Criteria for accreditation.

(a) *Scope.* (1) This section sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific tests.

(2) Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by NVLAP, depending upon the specific character of the task of the laboratory.

(3) This section is for use by testing laboratories in the development and implementation of their quality systems. It will also be used by NVLAP in the determination of the competence of laboratories.

(b) *Organization and management.* (1) The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Subpart.

(2) The laboratory shall:

(i) Have managerial staff with the authority and resources needed to discharge their duties;

(ii) Have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

(iii) Be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

(iv) Specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

(v) Provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

(vi) Have a technical manager (however named) who has overall responsibility for the technical operations;

(vii) Have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

(viii) Nominate deputies in case of absence of the technical or quality manager;

(ix) Have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

(x) Where appropriate, participate in interlaboratory comparisons and proficiency testing programs.

(c) *Quality system, audit and review.* (1) The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood,

and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this subpart. The quality manual and related quality documentation shall also contain:

(i) A quality policy statement, including objectives and commitments, by top management;

(ii) The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

(iii) The relations between management, technical operations, support services and the quality system;

(iv) Procedures for control and maintenance of documentation;

(v) Job descriptions of key staff and reference to the job descriptions of other staff;

(vi) Identification of the laboratory's approved signatories;

(vii) The laboratory's procedures for achieving traceability of measurements;

(viii) The laboratory's scope of calibrations and/or tests;

(ix) Arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

(x) Reference to the calibration, verification and/or test procedures used;

(xi) Procedures for handling calibration and test items;

(xii) Reference to the major equipment and reference measurement standards used;

(xiii) Reference to procedures for calibration, verification and maintenance of equipment;

(xiv) Reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

(xv) Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

(xvi) The laboratory management policies for departures from documented policies and procedures or from standard specifications;

(xvii) Procedures for dealing with complaints;

(xviii) Procedures for protecting confidentiality and proprietary rights;

(xix) Procedures for audit and review.

(xx) Policies and procedures directly related to compliance with this Subpart.

(3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

(4) The quality system adopted to satisfy the requirements of this Section shall be reviewed at least once each year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

(5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

(i) Internal quality control schemes using whenever possible statistical techniques;

(ii) Participation in proficiency testing or other interlaboratory comparisons;

(iii) Regular use of certified reference materials and/or in-house quality control using secondary reference materials;

(iv) Replicate testings using the same or different methods;

(v) Re-testing of retained items;

(vi) Correlation of results for different characteristics of an item.

(d) *Personnel.* (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

(3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) *Accommodation and environment.* (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

(2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

(3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

(4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

(5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

(6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

(f) *Equipment and reference materials.* (1) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Section are met.

(2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

(3) Each item of equipment including reference materials shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status.

(4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

(i) The name of the item of equipment;

(ii) The manufacturer's name, type identification, and serial number or other unique identification;

(iii) Date received and date placed in service;

(iv) Current location, where appropriate;

(v) Condition when received (e.g. new, used, reconditioned);

(vi) Copy of the manufacturer's instructions, where available;

(vii) Dates and results of calibrations and/or verifications and date of next calibration and/or verification;

(viii) Details of maintenance carried out to date and planned for the future;

(ix) History of any damage, malfunction, modification or repair.

(g) *Measurement traceability and calibration.* (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment.

(2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national

standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

(3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

(4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

(5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

(6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

(7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) *Calibration and test methods.* (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

(3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

(4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

(5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

(6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

(i) The requirements of this subpart are complied with;

(ii) Computer software is documented and adequate for use;

(iii) Procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

(iv) Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

(v) It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

(8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

(i) *Handling of calibration and test items.* (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

(2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard conditions as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

(3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

(4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

(j) *Records.* (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period as required in §280.7. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

(2) All records (including those listed in §280.215(f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

(k) *Certificates and reports.* (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

(2) Where the certificate or report contains results of calibrations or tests performed by sub-contractors, these results shall be clearly identified.

(3) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

(4) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement ''Supplement to Calibration Certificate for Test Report or Test Certificate, serial number * * * or as otherwise identified'', or equivalent form of wording. Such amendments shall meet all the relevant requirements of §280.215(j).

(5) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given

in any calibration certificate, test report or test certificate or amendment to a report or certificate.

(6) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Subpart are met and that confidentiality is preserved.

(l) *Subcontracting of calibration or testing.* (1) Where a laboratory sub-contracts any part of the calibration or testing, this work shall be placed with a laboratory accredited under either subparts C, D or E of this part for the specific tests being subcontracted. The laboratory shall comply with §280.9, and shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

(2) The laboratory shall record and retain details of its investigation of the accredited status and testing competence of subcontractors and maintain a register of all subcontracting.

(m) *Outside support services and supplies.* (1) Where the laboratory procures outside services and supplies, other than those referred to this Subpart, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

(2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) *Complaints.* (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

(2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with this section.

Subpart D—NIST Approval of Private Accreditation Programs

§280.300 Introduction.

In accordance with section 6(a)(1)(B) of the Act (15 U.S.C. 5405 (a)(1)(B)), this subpart sets forth the procedures and conditions under which private entities may apply for approval by NIST to engage directly in the accreditation of laboratories for the testing of fasteners under the Act.

§280.301 Application.

(a) Application must be made to NIST for approval to accredit laboratories for fastener testing under the Act. Upon request, NIST will provide application forms and instructions. The applicant shall complete the application in English and may provide whatever additional enclosures, attachments or exhibits the applicant deems appropriate.

(b) Application packages may be obtained from: Manager, FQA Accreditation Body Evaluation Program, NIST, Bldg. 820, Room 282, Gaithersburg, Maryland, 20899. Requests may be made by mail or by FAX to: (301) 963–2871.

(c) The applicant shall reimburse NIST for all costs incurred in the evaluation of its accreditation program and subsequent costs incurred in ensuring the continued compliance of its program. Reimbursement shall be in accordance with the fee schedule established by NIST for this purpose.

(d) An application may be revised by an applicant at any time prior to the final decision by NIST. An application may be withdrawn by an applicant,

without prejudice, at any time prior to the final decision by the Director.

§ 280.302 Review and decision process.

(a) Applications submitted by private laboratory accreditation bodies will be accepted by NIST and their receipt acknowledged in writing. The applications will be reviewed by NIST against the criteria specified in this subpart and in subpart F of this part. NIST may request additional information as needed from the applicant.

(b) NIST shall conduct on-site assessments of the facilities of the applicant including all of the applicant's organizational units and locations covered by the application.

(c) If the applicant's program is deemed by NIST to have met the requirements for approval, the applicant shall be notified by NIST in writing. The approval notice shall include the dates when the approval begins and the scope of the approval. The approval period shall be for as long as the laboratory accreditation body continues to satisfy the requirements of § 280.303. As part of maintaining its approved status, each laboratory accreditation body shall agree to be reassessed by NIST every two years following its initial notice of approval. NIST will maintain and make available to the public a list of approved fastener accreditation programs.

(d) If the applicant's program does not meet the requirements for approval, the applicant shall be notified in writing, listing the specific requirements from this subpart and subpart F of this part which the applicant's program has not met. After receipt of such a notification, and within the response period provided by NIST, the applicant may:

(1) Submit additional information for further review. Reviewing the new submission may involve additional on-site visits by NIST personnel. Additional fees may be required. Or,

(2) Submit a request that the original application be reconsidered, including a statement of reasons why the application should have been approved.

§ 280.303 Criteria for approval.

An applicant for NIST approval must demonstrate the ability to operate an accreditation program consistent with the requirements of this subpart and subparts A, B and F of this part.

§ 280.304 Maintaining approved status.

(a) Approved accreditation bodies shall continue to satisfy all the requirements of approval during the approval period.

(b) Upon request by NIST, approved accreditation bodies shall make available to NIST and BXA all records and materials pertaining to the program.

(c) NIST may elect to have its representative participate as an observer during on-site visits to testing laboratories seeking accreditation by an approved accreditation body.

(d) Neither the accreditation body, nor any laboratory it accredits under the Act and these regulations shall take any action which states or implies the approval, or endorsement by NIST or any other agency of the U.S. government of the results of tests carried out by such laboratories. In addition, neither the accreditation body, nor any laboratory it accredits under the Act and these regulations shall take any action which states or implies that the accreditation body or its accredited laboratories are recognized by NIST in any testing or other area(s) beyond those for which NIST has approved the accreditation body under this regulation. Approved accreditation bodies shall not engage in misrepresentation of the scope or conditions of its approval by NIST.

§ 280.305 Voluntary termination of approval.

At any time, an accreditation body may voluntarily terminate its program's approval by giving written notice to NIST and to all laboratories accredited by that body under its fastener laboratory accreditation program. The written notice shall state the date on which the termination will take effect.

§ 280.306 Involuntary termination of approval by NIST.

(a) NIST may terminate or suspend its approval of an accreditation body if such an action is deemed to be in the public interest.

(b) Before terminating the approval of an accreditation body, NIST will notify the accreditation body in writing, giving it the opportunity to rebut or correct the stated reasons for the proposed termination. If the problems are not corrected or reconciled within 30 days, or such longer time as NIST in its sole discretion may grant, the termination shall become effective.

(c) An accreditation body may appeal a termination to the Director by submitting a statement of reasons why the approval should not be terminated. NIST may, at its discretion, hold in abeyance the termination action pending a final decision by the Director. Within sixty days following receipt of the appeal, the Director shall inform the accreditation body in writing of his or her decision.

(d) Fastener testing laboratories which have been listed by NIST in accordance with subpart B of this part, based on their accreditation by an accreditation body whose approval has terminated, shall be removed from the list, unless an exception is granted by NIST.

Subpart E—Recognition of Foreign Laboratories

§ 280.400 Introduction.

In accordance with section 6(a)(1)(C) of the Act, this subpart sets forth the conditions under which the accreditation of foreign laboratories by their governments, by organizations acting on behalf of their governments, or by organizations recognized by the Director shall be deemed to meet the requirements of the Act.

§ 280.401 Recognition of foreign laboratories.

Foreign entities wishing to be recognized to accredit fastener testing laboratories must submit an application for evaluation to NIST. NIST recognition is limited to bodies that accredit laboratories performing tests on materials or fasteners covered by the Act. To be recognized by NIST, accredited foreign laboratories must meet conditions set out in subpart C of this part, and applicable laboratory accreditation bodies must meet conditions set out in subparts D and F of this part.

Subpart F—Requirements for Fastener Laboratory Accreditation Bodies

§ 280.500 Introduction.

This subpart sets out organizational, operational and other requirements that must be met by all accreditation bodies approved or recognized (hereafter ''approved/recognized'') by NIST under subpart D or E of this part. This subpart also sets out the requirements against which an approved/recognized accreditation body assesses the technical competence of an applicant testing laboratory. These requirements include conditions with respect to subpart C of this part.

§ 280.501 Accreditation bodies.

(a) *General provisions.* (1) The procedures under which an approved/recognized accreditation body operates shall be administered in a non-discriminatory manner. Access to an accreditation system operated by an approved/recognized accreditation body shall not be conditional upon the size of the laboratory or membership in any association or group, nor shall there be undue financial conditions to restrict participation.

(2) The competence of an applicant laboratory shall be assessed by an approved/recognized accreditation body against requirements consistent with the conditions set out in subpart C of this part.

(3) The requirements of § 280.501(a)(2) may have to be interpreted for a specific test or type of test by an approved/recognized accreditation body. These interpretations shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence. They shall be published by the accreditation body.

(4) An approved/recognized accreditation body shall require accredited laboratories to maintain impartiality and integrity.

(5) An approved/recognized accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.

(b) *Organization of an approved/recognized accreditation body.* (1) An approved/recognized accreditation body shall:

(i) Be a legally identifiable, public or private entity;

(ii) Have rights and responsibilities relevant to its accreditation activities;

(iii) Have adequate arrangements to cover liabilities arising from its operations and/or activities;

(iv) Have the financial stability and resources required for the operation of an accreditation system;

(v) Have and make available on request a description of the means by which it receives its financial support;

(vi) Employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed, under a senior executive who is responsible to the organization, body or board to which it reports;

(vii) Have a quality system including an organizational structure, that enables it to give confidence in its ability to operate a laboratory accreditation system satisfactorily;

(viii) Have documented policies and procedures for the operation of the quality system that include:

(A) Policies and decision-making procedures that distinguish between laboratory accreditation and any other activities in which the body is engaged;

(B) Policies and procedures for the resolution of complaints and appeals received from laboratories about the handling of accreditation matters, or from users of services about accredited laboratories or any other matters;

(ix) Together with its senior executive, and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;

(x) Have formal rules and structures for the appointment and operation of committees involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interest where no single interest predominates;

(xi) Establish one or more technical committees, each responsible, within its scope, for advising the accreditation body on the technical matters relating to the operation of its accreditation system;

(xii) Not offer consultancies or other services which may compromise the objectivity of its accreditation process and decisions;

(xiii) Have arrangements that are consistent with applicable laws, to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to applications, assessment and accreditation of laboratories;

(2) An approved/recognized accreditation body shall have arrangements for either controlling the ownership, use and display of the accreditation documents or controlling the manner in which an accredited laboratory may refer to its accredited status, or both.

(c) *Quality system.* (1) An approved/recognized accreditation body shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the accreditation body staff. The accreditation body shall designate a person having direct access to its highest executive level, to take responsibility for the quality system and the maintenance of the quality documentation.

(2) The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following;

(i) A quality policy statement;

(ii) The organizational structure of the accreditation body;

(iii) The operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;

(iv) Administrative procedures including document control;

(v) Policies and procedures to implement the accreditation process;

(vi) Arrangements for feedback and corrective actions whenever discrepancies are detected;

(vii) The policy and procedures for dealing with appeals, complaints and disputes;

(viii) The policy and procedures for conducting internal audits;

(ix) The policy and the procedures for conducting quality system reviews;

(x) The policy and the procedures for the recruitment and training of assessors and monitoring their performance.

(3) An approved/recognized accreditation body shall audit its activities to verify that they comply with the requirements of the quality system. The quality system shall also be reviewed to ensure its continued effectiveness. Audits and reviews shall be carried out systematically and periodically and recorded together with details of any corrective actions taken.

(4) An approved/recognized accreditation body shall maintain records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. These accreditation documents shall form part of the record.

(5) An approved/recognized accreditation body shall have a policy and procedures for retaining records. The records shall be retained for a period of at least 5 years, and shall be available to NIST personnel and other persons considered by the accreditation body to have a right of access to these records.

(d) *Granting, maintaining, extending, suspending, and withdrawing accreditation.* (1) An approved/recognized accreditation body shall specify the conditions for granting, maintaining and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total for all or part of the laboratory's scope of accreditation.

(2) An approved/recognized accreditation body shall have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation or require reassessment, in the event of changes affecting the laboratory's activity and operation, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the laboratory no longer complies with the requirements of the accreditation body.

(3) An approved/recognized accreditation body shall have arrangements relating to the transfer of accreditation when the legal status (e.g. ownership) of the accredited laboratory changes.

(e) *Documentation.* An approved/recognized accreditation body shall provide (through publications, electronic media or other means), update at adequate intervals, and make available on request:

(1) Information about the authority under which accreditation systems operated by the accreditation body were established and specifying whether they are mandatory or voluntary;

(2) A document containing its requirements for accreditation in accordance with this document;

(3) A document stating the arrangements for granting, maintaining, extending, suspending and withdrawing accreditation;

(4) Information about the assessment and accreditation process;

(5) General information on the fees charged to applicant and accredited laboratories;

(6) A description of the rights and duties of accredited laboratories as specified in § 280.504 of this part, including requirements, restrictions or limitations on the use of the accrediting body's logo and on the ways of referring to the accreditation granted.

§ 280.502 Laboratory assessors.

(a) *Requirements for assessors.* The assessor or assessment team appointed to assess a laboratory shall:

(1) Be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements;

(2) Have a thorough knowledge of the relevant assessment method and assessment documents;

(3) Have appropriate technical knowledge of the specific tests or types of tests for which accreditation is sought and, where relevant, with the associated sampling procedures;

(4) Be able to communicate effectively, both in writing and orally;

(5) Be free of any commercial, financial or other pressures or conflicts of interest that might cause assessor(s) to

act in other than an impartial or non-discriminatory manner;

(6) Not have offered consultancies to laboratories which might compromise their impartiality in the accreditation process and decisions.

(b) *Qualification procedures for assessors.* An approved/recognized accreditation body shall have an adequate procedure for:

(1) Qualifying assessors, comprising an assessment of their competence and training, and attendance at one or more actual assessments with a qualified assessor, and

(2) Monitoring the performance of assessors.

(c) *Contracting of assessors.* An approved/recognized accreditation body shall require the assessors to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation body, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior association with laboratories to be assessed.

(d) *Assessor records.* An approved/recognized accreditation body shall possess and maintain up-to-date records on assessors consisting of:

(1) Name and address;

(2) Organization affiliation and position held;

(3) Educational qualification and professional status;

(4) Work experience;

(5) Training in quality assurance, assessment and calibration and testing;

(6) Experience in laboratory assessment, together with field of competence;

(7) Date of most recent updating of record.

(e) *Procedures for assessors.* Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

§ 280.503 Accreditation process.

(a) *Application for accreditation.* (1) A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of accredited laboratories (including fees to be paid by applicant and accredited laboratories) shall be maintained up-to-date and given to applicant laboratories.

(2) Additional relevant information shall be provided to applicant laboratories on request.

(3) A duly authorized representative of the applicant laboratory shall be required to sign an official application form, in which or attached to which

(i) The scope of the desired accreditation is clearly defined;

(ii) The applicant's representative agrees to fulfill the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

(iii) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation of the laboratory.

(4)(i) The following minimum information shall be provided by the applicant laboratory prior to the on-site assessment:

(A) The general features of the applicant laboratory (corporate entity: Name, address, legal status, human and technical resources);

(B) General information concerning the laboratory covered by the application, such as primary function, relationship in a larger corporate entity and, If applicable, physical location of laboratories involved;

(C) A definition of the materials or products tested, the methods used and the tests performed;

(D) A copy of the laboratory's quality manual and, where required, the associated documentation.

(ii) The information gathered shall be used for the preparation of on-site assessment and shall be treated with appropriate confidentiality.

(b) *Assessment.* (1) An approved/recognized accreditation body shall appoint qualified assessor(s) to evaluate all material collected from the applicant and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

(2) To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.

(3) The date of assessment shall be mutually agreed with the applicant laboratory. The latter shall be informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment, with sufficient notice so that the laboratory is given an opportunity to appeal against the appointment of any particular assessor.

(4) The assessor(s) shall be formally appointed. A lead assessor shall be appointed, if relevant. The mandate given to the assessor(s) shall be clearly defined and made known to the applicant laboratory.

(c) *Sub-contracting of assessment.* (1) If an approved/recognized accreditation body decides to delegate fully or partially the assessment of a laboratory to another body, then the accreditation body shall take full responsibility for such an assessment made on its behalf.

(2) An approved/recognized accreditation body shall ensure that the party to which assessment has been delegated is approved/recognized by NIST.

(d) *Assessment report.* (1) An approved/recognized accreditation body may adopt reporting procedures that suit its needs but as a minimum these procedures shall ensure that:

(i) A meeting takes place between the assessor or assessment team and the laboratory management prior to leaving the laboratory at which the assessment team provides a written or oral report on the compliance of the applicant laboratory with the accreditation requirements;

(ii) The assessor or assessment team provides the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the applicant laboratory to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing;

(iii) A report on the outcome of the assessment is promptly brought to the applicant laboratory's notice by the accreditation body, identifying any non-compliances that have to be discharged in order to comply with all of the accreditation requirements. The laboratory shall be invited to present its comments on this report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any non-compliances with the accreditation requirements identified during the assessment.

(2) The final report authorized by an approved/recognized accreditation body and submitted to the laboratory, if it is different, shall include as a minimum:

(i) Date(s) of assessment(s);

(ii) The names of the person(s) responsible for the report;

(iii) The names and addresses of all the laboratory sites assessed;

(iv) The assessed scope of accreditation or reference thereto;

(v) comments of the assessor(s) or assessment team on the compliance of the applicant laboratory with the accreditation requirements.

(3) The reports shall take into consideration:

(i) The technical qualification, experience and authority of the staff encountered, especially the persons responsible for the technical validity of test reports or test certificates;

(ii) The adequacy of the internal organization and procedures adopted by the applicant laboratory to give confidence in the quality of its services, the physical facilities, i.e., the environment and the calibration/test equipment of the laboratory including maintenance and calibration having regard to the volume of work undertaken;

(iii) Proficiency testing or other interlaboratory comparison performed by the applicant laboratory, the results of this proficiency testing, and the use of these results by the laboratory;

(iv) The actions taken to correct any non-compliances identified at previous assessments.

(e) *Decision on accreditation.* (1) The decision whether or not to accredit a laboratory shall be taken by an approved/recognized accreditation body on the basis of the information gathered during the accreditation process.

(2) An approved/recognized accreditation body shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

(f) *Granting accreditation.* (1) An approved/recognized accreditation body

shall transmit to each accredited laboratory formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal accreditation documents shall permit identification of—

(i) The name and address of the laboratory that has been accredited;

(ii) The scope of the accreditation including:

(A) The tests or types of test for which accreditation has been granted;

(B) For tests, the materials or products tested, the methods used and the tests performed;

(C) For specific tests for which accreditation has been granted the methods used defined by written standards or reference documents that have been accepted by the accreditation body.

(iii) Where appropriate, the persons recognized by the accreditation body as being responsible for the test certificates or the test reports;

(iv) The term of accreditation which shall be valid for a period not to exceed three years;

(v) The accredited laboratory by a unique number.

(2) An approved/recognized accreditation body shall furnish notification to NIST required by Subpart B of this part.

(g) *Surveillance and reassessment of accredited laboratories.* (1) An approved/recognized accreditation body shall have an established documented program consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to ensure that its accredited laboratories continue to comply with the accreditation requirements.

(2) Surveillance and reassessment procedures shall be consistent with those concerning the assessment of laboratories as described in this Subpart.

(h) *Proficiency testing.* (1) The approved/recognized accreditation body shall require each fastener testing laboratory it accredits, and each laboratory which has applied to it for accreditation to participate in proficiency testing comparable to that conducted under Subpart C of this part by NVLAP.

(2) Although an accreditation shall not be granted or maintained only on the basis of the results of proficiency testing, accreditation shall not be granted or maintained if required proficiency testing participation is unsatisfactory.

(i) *Certificates or reports issued by accredited laboratories.* (1) An approved/recognized accreditation body shall normally allow an accredited laboratory to refer to its accreditation in test reports and test certificates that contain only the results of tests or types of test for which accreditation is held.

(2) An approved/recognized accreditation body shall have a policy that defines the circumstances in which accredited laboratories are permitted to include in test reports or test certificates, the results of tests for which accreditation is not held and the results of sub-contracted tests.

§ 280.504 Relationship between approved/recognized accreditation body and laboratory.

(a) An approved/recognized accreditation body shall have arrangements to ensure that the laboratory and its representatives afford such accommodation and co-operation as is necessary, to enable the accreditation body to verify compliance with the requirements for accreditation. These arrangements shall include provision for examination of documentation and access to all testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints.

(b) An approved/recognized accreditation body shall require that an accredited laboratory—

(1) At all times complies with the relevant provisions of these regulations;

(2) Claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

(3) Pays such fees as shall be determined by the accreditation body;

(4) Does not use its accreditation in such a manner as to bring the accreditation body into disrepute and does not make any statement relevant to its accreditation which the accreditation

body may consider misleading or unauthorized;

(5) Upon suspension or withdrawal of its accreditation (however determined) forthwith discontinues its use of all advertising matter that contains any reference thereto and return any certificates of accreditation to the accreditation body;

(6) Does not use its accreditation to state or imply any product approval by the accreditation body or any agency of the United States Government;

(7) Endeavors to ensure that no certificate or report nor any part thereof is used in a misleading manner;

(8) In making reference to its accreditation status in communication media such as advertising, brochures or other documents, complies with the requirements of the accreditation body.

(c) *Notification of change.* (1) An approved/recognized accreditation body shall have arrangements to ensure that an accredited laboratory informs it without delay of changes in any aspect of the laboratory's status or operation that affects the laboratory's:

(i) Legal, commercial or organizational status;

(ii) Organization and management, e.g., key managerial staff;

(iii) Policies or procedures, where appropriate;

(iv) Premises;

(v) Personnel, equipment, facilities, working environment or other resources, where significant;

(vi) Authorized signatories;

(vii) Or other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements in this document or any other relevant criteria of competence specified by the accreditation body.

(2) Upon receipt of due notice of any intended changes relating to the requirements of this document, the relevant criteria of competence and any other requirements prescribed by the accreditation body, the accreditation body shall ensure that the laboratory carries out the necessary adjustments to its procedures within such time, as in the opinion of the body is reasonable. The laboratory shall notify the body when such adjustments have been made.

(d) *Directory of accredited laboratories.* An approved/recognized accreditation body shall produce periodically but at least annually a directory of accredited laboratories describing the accreditation granted.

Subpart G—Enforcement

§ 280.600 Scope.

Section 280.601 of this part lists definitions used in this part. Section 280.602 of this part specifies that failure to take any action required by or taking any action prohibited by this part constitutes a violation of this part. Section 280.603 describes the penalties that may be imposed for violations of this part. Sections 280.605 through 280.623 establish the procedures for imposing administrative penalties for violations of this part.

§ 280.601 Definitions used in this subpart.

The definitions in this § 280.601 apply to this part.

Administrative law judge (ALJ). The person authorized to conduct hearings in administrative enforcement proceedings brought under the Act.

Assistant Secretary. The Assistant Secretary for Export Enforcement, Bureau of Export Administration.

Department. The United States Department of Commerce, specifically, the Bureau of Export Administration, NIST and the Patent and Trademark Office.

Final decision. A decision or order assessing a civil penalty or otherwise disposing of or dismissing a case, which is not subject to further review under this part, but which is subject to collection proceedings or judicial review in an appropriate Federal district court as authorized by law.

Initial decision. A decision of the administrative law judge which is subject to review by the Under Secretary for Export Administration, but which becomes the final decision of the Department in the absence of such an appeal.

Party. The Department and any person named as a respondent under this part.

Respondent. Any person named as the subject of a charging letter, proposed

charging letter, or other order proposed or issued under this part.

Under Secretary. The Under Secretary for Export Administration, United States Department of Commerce.

§ 280.602 Violations.

(a) *Engaging in prohibited conduct.* No person may engage in any conduct prohibited by or contrary to, or refrain from engaging in any action required by the Act, this part, or any order issued thereunder.

(b) *Causing, aiding, or abetting a violation.* No person may cause or aid, abet, counsel, command, induce, procure, or permit the doing of any act prohibited, or the omission of any act required, by the Act, this part, or any order issued thereunder.

(c) *Solicitation and attempt.* No person may solicit or attempt a violation of the Act, this part, or any order issued thereunder.

(d) *Conspiracy.* No person may conspire or act in concert with one or more persons in any manner or for any purpose to bring about or to do any act that constitutes a violation of the Act, this part, or any order issued thereunder.

(e) *Misrepresentation and concealment of facts.* No person may make any false or misleading representation, statement, or certification, or falsify or conceal any material fact, either directly to NIST, or the Bureau of Export Administration, the Patent and Trademark Office, or any official of any other United States agency, or indirectly through any other person:

(1) In the course of an investigation or other action subject to the Act and this part; or

(2) In connection with the preparation, submission, use, or maintenance of a laboratory test report, certificate of conformance as described in §§ 280.5 and 280.6 of this part, or any quality assurance system document required by this part or;

(3) In connection with any application for laboratory accreditation as described in § 280.205 of this part; or

(4) In connection with an application to be an accreditation body as described in § 280.301 of this part.

(f) *Falsification of test report.* No person shall falsify or make any false or misleading statement on or in connection with a laboratory test report required by section 5(c) of the Act or § 280.6 of this part.

(g) *Falsification of certificate of conformance.* No person shall falsify or make any false or misleading statement on or in connection with a certificate of conformance required by § 280.5 of this part.

(h) *Falsification of documents relating to accreditation of laboratories or registrars or approval or recognition of accreditors or accreditation bodies.* No person shall falsify or make any false or misleading statement on or in connection with any document relating to laboratory accreditation or approval or recognition of accreditation bodies, Accreditors or Registrars as required by section 6(a) or 6(b) of the Act or this part.

(i) *Use of another person's recorded insignia.* No person may apply an insignia to a fastener if the Commissioner has issued a certificate of recordal (as described in § 280.712 of this part) for that insignia to another person without written permission from the person to whom the certificate was issued.

(j) *Falsification of laboratory accreditation, accreditation body or accreditor.* No person shall falsely claim to be an accredited laboratory or approved or recognized accreditation body or Accreditor as described in section 6 of the Act or subparts B, C, D, E, I and J of this part.

(k) *Sale of fasteners manufactured prior to the implementation date as compliant with the Act.* No person shall represent, sell, or offer for sale fasteners manufactured prior to June 1, 1999, as being in conformance with the Act or this part except as provided for in § 280.12(d) or (e) of this part.

(l) *Failure to assign lot number traceable to manufacturer's single, unique lot number.* No importer, distributor, or significant alterer shall assign a lot number unless the assigned lot number is traceable to a manufacturer's single, unique lot number.

(m) *Falsification of documents relating to the registration of fastener manufacturing facilities as accredited laboratories, accreditation of registrars or recognition of accreditors.* No person shall falsify or

make any false or misleading statement on or in connection with any document relating to the registration of Fastener Manufacturing Facilities as accredited laboratories, accreditation of Registrars or recognition of Accreditors as required by subparts I, J, K, and L of this part.

(n) *False claim of registration of fastener manufacturing facilities as accredited laboratories, accreditation of registrars, and recognition of accreditors.* No person shall falsely claim to be a registered Fastener Manufacturing Facility, an accredited Registrar, or a recognized Accreditor as described by subparts I, J, K, and L of this part.

(o) *Falsification of documents relating to the certification of FQA compliance required for provisional listing on the Facilities List.* No person shall falsify or make any false or misleading statement on or in connection with any document relating to the certification of FQA compliance required for provisional listing on the Facilities List pursuant to §280.810(c)(3).

[61 FR 50558, Sept. 26, 1996, as amended at 63 FR 18275, Apr. 14, 1998; 63 FR 34965, June 26, 1998; 63 FR 51526, Sept. 28, 1998]

§280.603 Penalties, remedies, and sanctions.

(a) *Civil remedies.* The Attorney General may bring an action in an appropriate United States district court for declaratory and injunctive relief against any person who violates the Act or any regulation issued thereunder. Such action may not be brought more than 10 years after the cause of action accrues.

(b) *Civil penalties.* Any person who is determined, after notice and opportunity for a hearing, to have violated the Act or any regulation issued thereunder shall be liable to the United States for a civil penalty of not more than $25,000 for each violation.

(c) *Criminal penalties.* (1) Whoever knowingly certifies, marks, offers for sale, or sells a fastener in violation of the Act or a regulation issued thereunder shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

(2) Whoever intentionally fails to maintain records relating to a fastener in violation of the Act or a regulation issued thereunder shall be fined under title 18, United States Code, or imprisoned not more than five years or both.

(3) Whoever negligently fails to maintain records relating to a fastener in violation of the Act or a regulation issued thereunder shall be fined under title 18, United States Code, or imprisoned not more than two years or both.

§280.604 Administrative enforcement proceedings.

Sections 280.605 through 280.623 set forth the procedures for imposing administrative penalties for violations of the Act and Fastener Quality Regulations (FQR).

§280.605 Institution of administrative enforcement proceedings.

(a) *Charging letters.* The Director of the Office of Export Enforcement (OEE) may begin administrative enforcement proceedings under this part by issuing a charging letter. The charging letter shall constitute the formal complaint and will state that there is reason to believe that a violation of this part has occurred. It will set forth the essential facts about each alleged violation, refer to the specific regulatory or other provisions involved, and give notice of the sanctions available under the Act and this part. The charging letter will inform the respondent that failure to answer the charges as provided in §280.608 of this part will be treated as a default under §280.609 of this part, that the respondent is entitled to a hearing if a written demand for one is requested with the answer, and that the respondent may be represented by counsel, or by other authorized representative. A copy of the charging letter shall be filed with the administrative law judge, which filing shall toll the running of the applicable statute of limitations. Charging letters may be amended or supplemented at any time before an answer is filed, or, with permission of the administrative law judge, afterwards. The Department may unilaterally withdraw charging letters at any time, by notifying the respondent and the administrative law judge.

(b) *Notice of issuance of charging letter instituting administrative enforcement*

proceeding. A respondent shall be notified of the issuance of a charging letter, or any amendment or supplement thereto:

(1) By mailing a copy by registered or certified mail addressed to the respondent at the respondent's last known address;

(2) By leaving a copy with the respondent or with an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process for the respondent; or

(3) By leaving a copy with a person of suitable age and discretion who resides at the respondent's last known dwelling.

(4) Delivery of a copy of the charging letter, if made in the manner described in paragraph (b)(2) or (3) of this section, shall be evidenced by a certificate of service signed by the person making such service, stating the method of service and the identity of the person with whom the charging letter was left. The certificate of service shall be filed with the administrative law judge.

(c) *Date.* The date of service of notice of the issuance of a charging letter instituting an administrative enforcement proceeding, or service of notice of the issuance of a supplement or amendment to a charging letter, is the date of its delivery, or of its attempted delivery if delivery is refused.

§ 280.606 Representation.

A respondent individual may appear and participate in person, a corporation by a duly authorized officer or employee, and a partnership by a partner. If a respondent is represented by counsel, counsel shall be a member in good standing of the bar of any State, Commonwealth or Territory of the United States, or of the District of Columbia, or be licensed to practice law in the country in which counsel resides if not the United States. A respondent personally, or through counsel or other representative who has the power of attorney to represent the respondent, shall file a notice of appearance with the administrative law judge. The Department will be represented by the Office of Chief Counsel for Export Administration, U.S. Department of Commerce.

§ 280.607 Filing and service of papers other than charging letter.

(a) *Filing.* All papers to be filed shall be addressed to ''FQA Administrative Enforcement Proceedings,'' at the address set forth in the charging letter, or such other place as the administrative law judge may designate. Filing by United States mail, first class postage prepaid, by express or equivalent parcel delivery service, or by hand delivery, is acceptable. Filing by mail from a foreign country shall be by airmail. In addition, the administrative law judge may authorize filing of papers by facsimile or other electronic means, provided that a hard copy of any such paper is subsequently filed. A copy of each paper filed shall be simultaneously served on each party.

(b) *Service.* Service shall be made by personal delivery or by mailing one copy of each paper to each party in the proceeding. Service by delivery service or facsimile, in the manner set forth in paragraph (a) of this section, is acceptable. Service on the Department shall be addressed to the Chief Counsel for Export Administration, Room H–3839, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC. 20230. Service on a respondent shall be to the address to which the charging letter was sent or to such other address as respondent may provide. When a party has appeared by counsel or other representative, service on counsel or other representative shall constitute service on that party.

(c) *Date.* The date of filing or service is the day when the papers are deposited in the mail or are delivered in person, by delivery service, or by facsimile.

(d) *Certificate of service.* A certificate of service signed by the party making service, stating the date and manner of service, shall accompany every paper, other than the charging letter, filed and served on parties.

(e) *Computing period of time.* In computing any period of time prescribed or allowed by this part or by order of the administrative law judge or the Under Secretary, the day of the act, event, or

default from which the designated period of time begins to run is not to be included. The last day of the period so computed is to be included unless it is a Saturday, a Sunday, or a legal holiday (as defined in Rule 6(a) of the Federal Rules of Civil Procedure), in which case the period runs until the end of the next day which is neither a Saturday, a Sunday, nor a legal holiday. Intermediate Saturdays, Sundays, and legal holidays are excluded from the computation when the period of time prescribed or allowed is seven days or less.

§ 280.608 Answer and demand for hearing.

(a) *When to answer.* The respondent must answer the charging letter within 30 days after being served with notice of the issuance of a charging letter instituting an administrative enforcement proceeding, or within 30 days of notice of any supplement or amendment to a charging letter, unless time is extended under § 280.618 of this part.

(b) *Contents of answer.* The answer must be responsive to the charging letter and must fully set forth the nature of the respondent's defense or defenses. The answer must admit or deny specifically each separate allegation of the charging letter; if the respondent is without knowledge, the answer must so state and will operate as a denial. Failure to deny or controvert a particular allegation will be deemed an admission of that allegation. The answer must also set forth any additional or new matter the respondent believes supports a defense or claim of mitigation. Any defense or partial defense not specifically set forth in the answer shall be deemed waived, and evidence thereon may be refused, except for good cause shown.

(c) *Demand for hearing.* If the respondent desires a hearing, a written demand for one must be submitted with the answer. Any demand by the Department for a hearing must be filed with the administrative law judge within 30 days after service of the answer. Failure to make a timely written demand for a hearing shall be deemed a waiver of the party's right to a hearing, except for good cause shown. If no party demands a hearing, the matter will go forward in accordance with the procedures set forth in § 280.617 of this part.

(d) *English language required.* The answer, all other papers, and all documentary evidence must be submitted in English, or translations into English must be filed and served at the same time.

§ 280.609 Default.

(a) *General.* Failure of the respondent to file an answer within the time provided constitutes a waiver of the respondent's right to appear and contest the allegations in the charging letter. In such event, the administrative law judge, on the Department's motion and without further notice to the respondent, shall find the facts to be as alleged in the charging letter and render an initial decision containing findings of fact and appropriate conclusions of law and issue an initial decision and order imposing appropriate sanctions. The decision and order may be appealed to the Under Secretary in accordance with the applicable procedures set forth in § 280.623 of this part.

(b) *Petition to set aside default*—(1) *Procedure.* Upon petition filed by a respondent against whom a default order has been issued, which petition is accompanied by an answer meeting the requirements of 280.608(b) of this part, the Under Secretary may, after giving all parties an opportunity to comment, and for good cause shown, set aside the default and vacate the order entered thereon and remand the matter to the administrative law judge for further proceedings.

(2) *Time limits.* A petition under this section must be made within one year of the date of entry of the order which the petition seeks to have vacated.

§ 280.610 Summary decision.

At any time after a proceeding has been initiated, a party may move for a summary decision disposing of some or all of the issues. The administrative law judge may render an initial decision and issue an order if the entire record shows, as to the issue(s) under consideration:

(a) That there is no genuine issue as to any material fact; and

(b) That the moving party is entitled to a summary decision as a matter of law.

§ 280.611 Discovery.

(a) *General.* The parties are encouraged to engage in voluntary discovery regarding any matter, not privileged, which is relevant to the subject matter of the pending proceeding. The provisions of the Federal Rules of Civil Procedure relating to discovery apply to the extent consistent with this part and except as otherwise provided by the administrative law judge or by waiver or agreement of the parties. The administrative law judge may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. These orders may include limitations on the scope, method, time and place of discovery, and provisions for protecting the confidentiality of classified or otherwise sensitive information.

(b) *Interrogatories and requests for admission or production of documents.* A party may serve on any party interrogatories, requests for admission, or requests for production of documents for inspection and copying, and a party concerned may apply to the administrative law judge for such enforcement or protective order as that party deems warranted with respect to such discovery. The service of a discovery request shall be made at least 20 days before the scheduled date of the hearing unless the administrative law judge specifies a shorter time period. Copies of interrogatories, requests for admission and requests for production of documents and responses thereto shall be served on all parties, and a copy of the certificate of service shall be filed with the administrative law judge. Matters of fact or law of which admission is requested shall be deemed admitted unless, within a period designated in the request (at least 10 days after service, or within such additional time as the administrative law judge may allow), the party to whom the request is directed serves upon the requesting party a sworn statement either denying specifically the matters of which admission is requested or setting forth in detail the reasons why the party to whom the request is directed cannot truthfully either admit or deny such matters.

(c) *Depositions.* Upon application of a party and for good cause shown, the administrative law judge may order the taking of the testimony of any person by deposition and the production of specified documents or materials by the person at the deposition. The application shall state the purpose of the deposition and set forth the facts sought to be established through the deposition.

(d) *Enforcement.* The administrative law judge may order a party to answer designated questions, to produce specified documents or things or to take any other action in response to a proper discovery request. If a party does not comply with such an order, the administrative law judge may make a determination or enter any order in the proceeding as the ALJ deems reasonable and appropriate. The ALJ may strike related charges or defenses in whole or in part or may take particular facts relating to the discovery request to which the party failed or refused to respond as being established for purposes of the proceeding in accordance with the contentions of the party seeking discovery. In addition, enforcement by a district court of the United States may be sought under section 9(b)(6) of the Act.

§ 280.612 Subpoenas.

(a) *Issuance.* Upon the application of any party, supported by a satisfactory showing that there is substantial reason to believe that the evidence would not otherwise be available, the administrative law judge may issue subpoenas requiring the attendance and testimony of witnesses and the production of such books, records or other documentary or physical evidence for the purpose of the hearing, as the ALJ deems relevant and material to the proceedings, and reasonable in scope. Witnesses summoned shall be paid the same fees and mileage that are paid to witnesses in the courts of the United States. In case of contempt or refusal to obey a subpoena served upon any person pursuant to this paragraph, the district court of the United States for any district in which such person is

found, resides, or transacts business, upon application by the United States and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the administrative law judge or to appear and produce documents before the administrative law judge, or both, and any failure to obey such order of the court may be punished by such court as contempt thereof.

(b) *Service.* Subpoenas issued by the administrative law judge may be served in any of the methods set forth in § 280.607(b) of this part.

(c) *Timing.* Applications for subpoenas must be submitted at least 10 days before the scheduled hearing or deposition, unless the administrative law judge determines, for good cause shown, that extraordinary circumstances warrant a shorter time.

§ 280.613 Matter protected against disclosure.

(a) *Protective measures.* The administrative law judge may limit discovery or introduction of evidence or issue such protective or other orders as in the ALJ's judgment may be needed to prevent undue disclosure of classified or sensitive documents or information. Where the administrative law judge determines that documents containing the classified or sensitive matter need to be made available to a party to avoid prejudice, the ALJ may direct that an unclassified and/or nonsensitive summary or extract of the documents be prepared. The administrative law judge may compare the extract or summary with the original to ensure that it is supported by the source document and that it omits only so much as must remain undisclosed. The summary or extract may be admitted as evidence in the record.

(b) *Arrangements for access.* If the administrative law judge determines that this procedure is unsatisfactory and that classified or otherwise sensitive matter must form part of the record in order to avoid prejudice to a party, the administrative law judge may provide the parties an opportunity to make arrangements that permit a party or a representative to have access to such matter without compromising sensitive information. Such arrangements may include obtaining security clearances or giving counsel for a party access to sensitive information and documents subject to assurances against further disclosure, including a protective order, if necessary.

§ 280.614 Prehearing conference.

(a) The administrative law judge, on his or her own motion or on request of a party, may direct the parties to participate in a prehearing conference, either in person or by telephone, to consider:

(1) Simplification of issues;

(2) The necessity or desirability of amendments to pleadings;

(3) Obtaining stipulations of fact and of documents to avoid unnecessary proof; or

(4) Such other matters as may expedite the disposition of the proceedings.

(b) The administrative law judge may order the conference proceedings to be recorded electronically or taken by a reporter, transcribed and filed with the ALJ.

(c) If a prehearing conference is impracticable, the administrative law judge may direct the parties to correspond with the ALJ to achieve the purposes of such a conference.

(d) The administrative law judge will prepare a summary of any actions agreed on or taken pursuant to this section. The summary will include any written stipulations or agreements made by the parties.

§ 280.615 Hearings.

(a) *Scheduling.* The administrative law judge, by agreement with the parties or upon notice to all parties of not less than 30 days, will schedule a hearing. All hearings will be held in Washington, DC., unless the administrative law judge determines, for good cause shown, that another location would better serve the interests of justice.

(b) *Hearing procedure.* Hearings will be conducted in a fair and impartial manner by the administrative law judge, who may limit attendance at any hearing or portion thereof to the parties, their representatives and witnesses if the administrative law judge deems this necessary or advisable in order to protect sensitive matter (see

§ 280.613 of this part) from improper disclosure. The rules of evidence prevailing in courts of law do not apply, and all evidentiary material deemed by the administrative law judge to be relevant and material to the proceeding and not unduly repetitious will be received and given appropriate weight.

(c) *Testimony and record.* Witnesses will testify under oath or affirmation. A verbatim record of the hearing and of any other oral proceedings will be taken by reporter or by electronic recording, transcribed and filed with the administrative law judge. A respondent may examine the transcript and may obtain a copy by paying any applicable costs. Upon such terms as the administrative law judge deems just, the ALJ may direct that the testimony of any person be taken by deposition and may admit an affidavit or declaration as evidence, provided that any affidavits or declarations have been filed and served on the parties sufficiently in advance of the hearing to permit a party to file and serve an objection thereto on the grounds that it is necessary that the affiant or declarant testify at the hearing and be subject to cross-examination.

(d) *Failure to appear.* If a party fails to appear in person or by counsel at a scheduled hearing, the hearing may nevertheless proceed, and that party's failure to appear will not affect the validity of the hearing or any proceedings or action taken thereafter.

§ 280.616 Interlocutory review of rulings.

(a) At the request of a party, or on the administrative law judge's own initiative, the administrative law judge may certify to the Under Secretary for review a ruling that does not finally dispose of a proceeding, if the administrative law judge determines that immediate review may hasten or facilitate the final disposition of the matter.

(b) Upon certification to the Under Secretary of the interlocutory ruling for review, the parties will have 10 days to file and serve briefs stating their positions, and five days to file and serve replies, following which the Under Secretary will decide the matter promptly.

§ 280.617 Proceeding without a hearing.

If the parties have waived a hearing, the case will be decided on the record by the administrative law judge. Proceeding without a hearing does not relieve the parties from the necessity of proving the facts supporting their charges or defenses. Affidavits or declarations, depositions, admissions, answers to interrogatories and stipulations may supplement other documentary evidence in the record. The administrative law judge will give each party reasonable opportunity to file rebuttal evidence.

§ 280.618 Procedural stipulations; extension of time.

(a) *Procedural stipulations.* Unless otherwise ordered, a written stipulation agreed to by all parties and filed with the administrative law judge will modify any procedures established by this part.

(b) *Extension of time.* (1) The parties may extend any applicable time limitation, by stipulation filed with the administrative law judge before the time limitation expires.

(2) The administrative law judge may, on the judge's own initiative or upon application by any party, either before or after the expiration of any applicable time limitation, extend the time within which to file and serve an answer to a charging letter or do any other act required by this part.

§ 280.619 Decision of the administrative law judge.

(a) *Predecisional matters.* Except for default proceedings under § 280.609 of this part, the administrative law judge will give the parties reasonable opportunity to submit the following, which will be made a part of the record:

(1) Exceptions to any ruling by the judge or to the admissibility of evidence proffered at the hearing;

(2) Proposed findings of fact and conclusions of law;

(3) Supporting legal arguments for the exceptions and proposed findings and conclusions submitted; and

(4) A proposed order.

(b) *Decision and order.* After considering the entire record in the proceeding, the administrative law judge

will issue a written initial decision. The decision will include findings of fact, conclusions of law, and findings as to whether there has been a violation of the Act, this part, or any order issued thereunder. If the administrative law judge finds that the evidence of record is insufficient to sustain a finding that a violation has occurred with respect to one or more charges, the ALJ shall order dismissal of the charges in whole or in part, as appropriate. If the administrative law judge finds that one or more violations have been committed, the ALJ may issue an order imposing administrative sanctions, as provided in this part. The decision and order shall be served on each party, and shall become effective as the final decision of the Department 30 days after service, unless an appeal is filed in accordance with §280.623 of this part. In determining the amount of any civil penalty the ALJ shall consider the nature, circumstances and gravity of the violation and, with respect to the person found to have committed the violation, the degree of culpability, any history of prior violations, the effect on ability to continue to do business, any good faith attempt to achieve compliance, ability to pay the penalty, and such other matters as justice may require.

(c) *Suspension of sanctions.* Any order imposing administrative sanctions may provide for the suspension of the sanction imposed, in whole or in part and on such terms of probation or other conditions as the administrative law judge or the Under Secretary may specify. Any suspension order may be modified or revoked by the signing official upon application by the Department showing a violation of the probationary terms or other conditions, after service on the respondent of notice of the application in accordance with the service provisions of §280.607 of this part, and with such opportunity for response as the responsible signing official in his/her discretion may allow. A copy of any order modifying or revoking the suspension shall also be served on the respondent in accordance with the provisions of §280.607 of this part.

§ 280.620 Settlement.

(a) *Cases may be settled before service of a charging letter.* In cases in which settlement is reached before service of a charging letter, a proposed charging letter will be prepared, and a settlement proposal consisting of a settlement agreement and order will be submitted to the Assistant Secretary for approval and signature. If the Assistant Secretary does not approve the proposal, he/she will notify the parties and the case will proceed as though no settlement proposal had been made. If the Assistant Secretary approves the proposal, he/she will issue an appropriate order, and no action will be required by the administrative law judge.

(b) *Cases may also be settled after service of a charging letter.* (1) If the case is pending before the administrative law judge, the ALJ shall stay the proceedings for a reasonable period of time, usually not to exceed 30 days, upon notification by the parties that they have entered into good faith settlement negotiations. The administrative law judge may, in his/her discretion, grant additional stays. If settlement is reached, a proposal will be submitted to the Assistant Secretary for approval and signature. If the Assistant Secretary approves the proposal, he/she will issue an appropriate order, and notify the administrative law judge that the case is withdrawn from adjudication. If the Assistant Secretary does not approve the proposal, he/she will notify the parties and the case will proceed to adjudication by the administrative law judge as though no settlement proposal had been made.

(2) If the case is pending before the Under Secretary under §280.623 of this part, the parties may submit a settlement proposal to the Under Secretary for approval and signature. If the Under Secretary approves the proposal, he/she will issue an appropriate order. If the Under Secretary does not approve the proposal, the case will proceed to final decision in accordance with Section 280.623 of this part, as appropriate.

(c) Any order disposing of a case by settlement may suspend the administrative sanction imposed, in whole or in part, on such terms of probation or other conditions as the signing official

may specify. Any such suspension may be modified or revoked by the signing official, in accordance with the procedures set forth in §280.619(c) of this part.

(d) Any respondent who agrees to an order imposing any administrative sanction does so solely for the purpose of resolving the claims in the administrative enforcement proceeding brought under this part. This reflects the fact that the Department has neither the authority nor the responsibility for instituting, conducting, settling, or otherwise disposing of criminal proceedings. That authority and responsibility is vested in the Attorney General and the Department of Justice.

(e) Cases that are settled may not be reopened or appealed.

§280.621 Reopening.

The respondent may petition the administrative law judge within one year of the date of the final decision, except where the decision arises from a default judgment or from a settlement, to reopen an administrative enforcement proceeding to receive any relevant and material evidence which was unknown or unobtainable at the time the proceeding was held. The petition must include a summary of such evidence, the reasons why it is deemed relevant and material, and the reasons why it could not have been presented at the time the proceedings were held. The administrative law judge will grant or deny the petition after providing other parties reasonable opportunity to comment. If the proceeding is reopened, the administrative law judge may make such arrangements as the ALJ deems appropriate for receiving the new evidence and completing the record. The administrative law judge will then issue a new initial decision and order, and the case will proceed to final decision and order in accordance with §280.623 of this part.

§280.622 Record for decision and availability of documents.

(a) *General.* The transcript of hearings, exhibits, rulings, orders, all papers and requests filed in the proceedings and, for purposes of any appeal under §280.623 of this part, the decision of the administrative law judge and such submissions as are provided for by §280.623 of this part, will constitute the record and the exclusive basis for decision. When a case is settled after the service of a charging letter, the record will consist of any and all of the foregoing, as well as the settlement agreement and the order. When a case is settled before service of a charging letter, the record will consist of the proposed charging letter, the settlement agreement and the order.

(b) *Restricted access.* On the administrative law judge's own motion, or on the motion of any party, the administrative law judge may direct that there be a restricted access portion of the record for any material in the record to which public access is restricted by law or by the terms of a protective order entered in the proceedings. A party seeking to restrict access to any portion of the record is responsible for submitting, at the time specified in §280.622(c)(2) of this part, a version of the document proposed for public availability that reflects the requested deletion. The restricted access portion of the record will be placed in a separate file and the file will be clearly marked to avoid improper disclosure and to identify it as a portion of the official record in the proceedings. The administrative law judge may act at any time to permit material that becomes declassified or unrestricted through passage of time to be transferred to the unrestricted access portion of the record.

(c) *Availability of documents*—(1) *Scope.* All charging letters, answers, initial decisions, and orders disposing of a case will be made available for public inspection in the BXA Freedom of Information Records Inspection Facility, U.S. Department of Commerce, Room H–6624, 14th Street and Pennsylvania Avenue, NW, Washington, DC 20230. The complete record for decision, as defined in paragraphs (a) and (b) of this section will be made available on request.

(2) *Timing.* Documents are available immediately upon filing, except for any portion of the record for which a request for segregation is made. Parties that seek to restrict access to any portion of the record under paragraph

(b) of this section must make such a request, together with the reasons supporting the claim of confidentiality, simultaneously with the submission of material for the record.

§ 280.623 Appeals.

(a) *Grounds.* A party may appeal to the Under Secretary from an order disposing of a proceeding or an order denying a petition to set aside a default or a petition for reopening, on the grounds:

(1) That a necessary finding of fact is omitted, erroneous or unsupported by substantial evidence of record;

(2) That a necessary legal conclusion or finding is contrary to law;

(3) That prejudicial procedural error occurred; or

(4) That the decision or the extent of sanctions is arbitrary, capricious or an abuse of discretion. The appeal must specify the grounds on which the appeal is based and the provisions of the order from which the appeal is taken.

(b) *Filing of appeal.* An appeal from an order must be filed with the Office of the Under Secretary for Export Administration, Bureau of Export Administration, U.S. Department of Commerce, Room H–3898, 14th Street and Constitution Avenue, NW., Washington, DC 20230, within 30 days after service of the order appealed from. If the Under Secretary cannot act on an appeal for any reason, the Under Secretary will designate another Department of Commerce official to receive and act on the appeal.

(c) *Effect of appeal.* The filing of an appeal shall not stay the operation of any order, unless the order by its express terms so provides or unless the Under Secretary, upon application by a party and with opportunity for response, grants a stay.

(d) *Appeal procedure.* The Under Secretary normally will not hold hearings or entertain oral argument on appeals. A full written statement in support of the appeal must be filed with the appeal and be simultaneously served on all parties, who shall have 30 days from service to file a reply. At his/her discretion, the Under Secretary may accept new submissions, but will not ordinarily accept those submissions filed more than 30 days after the filing of the reply to the appellant's first submission.

(e) *Decisions.* The decision will be in writing and will be accompanied by an order signed by the Under Secretary giving effect to the decision. The order may either dispose of the case by affirming, modifying or reversing the order of the administrative law judge or may refer the case back to the administrative law judge for further proceedings.

(f) *Delivery.* The final decision and implementing order shall be served on the parties and will be publicly available in accordance with § 280.622 of this part.

(g) *Judicial review.* The charged party may appeal the Under Secretary's written order within 30 days to the appropriate United States District Court pursuant to section 9(b)(3) of the Act (15 U.S.C. 5408(b)(3)) by filing a notice of appeal in such court within 30 days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Chief Counsel for Export Administration, Room H–3839, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. The findings and order of the Under Secretary shall be set aside by such court if they are found to be unsupported by substantial evidence, as provided in section 706(2) of title 5 United States Code.

Subpart H—Recordal of Insignia

§ 280.700 Recorded insignia required prior to offer for sale.

(a) Any manufacturer or private label distributor of a fastener must, prior to any sale or offer for sale of any fastener which is required by the standards and specifications by which it is manufactured to bear a raised or depressed insignia identifying its manufacturer or private label distributor, apply for and record an insignia to be applied to any fastener which is to be sold or offered for sale to ensure that each fastener may be traced to its manufacturer or private label distributor.

(b) The manufacturer's or private label distributor's insignia must be applied to any fastener which is sold or

offered for sale if such fastener is required by the standards and specification by which it is manufactured to bear a raised or depressed insignia identifying its manufacturer or private label distributor. If the fastener has no head, the insignia must be applied to another surface area in a legible manner.

(c) The insignia must be applied through a raised or depressed impression. The insignia must be readable with no greater than 10x magnification.

THE WRITTEN APPLICATION

§ 280.710 Applications for insignia.

(a) Each manufacturer or private label distributor must submit a written application for recordal of an insignia on the Fastener Insignia Register along with the prescribed fee. The application must be in a form prescribed by the Commissioner.

(b) The written application must be in the English language and must include the following:

(1) The name of the applicant;

(2) The address of the applicant;

(3) The entity, domicile, and state of incorporation, if applicable, of the applicant;

(4) Either:

(i) A request for recordal and issuance of a unique alphanumeric designation by the Commissioner, or

(ii) A request for recordal of a trademark, which is the subject of either a duly filed application or a registration for fasteners in the name of the applicant in the U.S. Patent and Trademark Office on the Principal Register, indicating the application serial number or registration number and accompanied by a copy of the drawing page of the application or a copy of the registration;

(5) A statement that the applicant will comply with the applicable provisions of the Fastener Quality Act;

(6) A statement that the person signing the application on behalf of the applicant has personal knowledge of the facts relevant to the application and that the person possesses the authority to act on behalf of the applicant;

(7) A verification stating that the person signing declares under penalty of perjury under the laws of the United States of America that the information and statements included in the application are true and correct; and

(8) The application fee.

(c) An applicant may designate only one registered trademark for recordal on the Fastener Insignia Register in a single application. The trademark application or registration which forms the basis for the fastener recordal must be in active status, that is a pending application or a registration which is not expired, abandoned or canceled, at the time of the application for recordal.

(d) Applications and other documents should be addressed to: Box Fastener, Commissioner of Patents and Trademarks, Washington DC 20231.

§ 280.711 Review of the application.

The Commissioner will review the application for compliance with § 280.710. If the application does not contain one or more of the elements required by § 280.710, the Commissioner will not issue a certificate of recordal, and will return the papers and fees. The Commissioner will notify the applicant of any defect in the application. Applications for recordal of an insignia may be re-submitted to the Commissioner at any time.

§ 280.712 Certificate of recordal.

If the application complies with the requirements of § 280.710, the Commissioner shall accept the application and issue a certificate of recordal. Such certificate shall be issued in the name of the United States of America, under the seal of the Patent and Trademark Office, and a record shall be kept in the Patent and Trademark Office. The certificate of recordal shall display the recorded insignia of the applicant, and state the name, address, legal entity and domicile of the applicant, as well as the date of issuance of such certificate.

§ 280.713 Recordal of additional insignia.

(a) A manufacturer or private label distributor to whom the Commissioner has issued an alphanumeric designation may apply for recordal of its

trademark for fasteners if the trademark is the subject of a duly filed application or is registered in the U.S. Patent and Trademark Office on the Principal Register. Upon recordal, either the alphanumeric designation or the registered mark, or both, may be used as recorded insignias.

(b) A manufacturer or private label distributor for whom the Commissioner has recorded a trademark as its fastener insignia, may apply for issuance and recordal of an alphanumeric designation as a fastener insignia. Upon recordal, either the alphanumeric designation or the trademark, or both, may be used as recorded insignias.

POST-RECORDAL MAINTENANCE

§ 280.720 Maintenance of the certificate of recordal.

(a) Certificates of recordal remain in an active status for five years and may be maintained in an active status for five-year periods running consecutively from the date of issuance of the certificate of recordal upon compliance with the requirements of § 280.720(c).

(b) Maintenance applications shall be required only if the holder of the certificate of recordal is a manufacturer or private label distributor at the time the maintenance application is required.

(c) Certificates of recordal will be designated as inactive unless, within six months prior to the expiration of each five-year period running consecutively from the date of issuance, the certificate holder files the prescribed maintenance fee and the maintenance application. The maintenance application must be in the English language and must include the following:

(1) The name of the applicant;

(2) The address of the applicant;

(3) The entity, domicile, and state of incorporation, if applicable, of the applicant;

(4) A copy of applicant's certificate of recordal;

(5) A statement that the applicant will comply with the applicable provisions of the Fastener Quality Act;

(6) A statement that the person signing the application on behalf of the applicant has knowledge of the facts relevant to the application and that the person possesses the authority to act on behalf of the applicant;

(7) A verification stating that the person signing declares under penalty of perjury under the laws of the United States of America that the information and statements included in the application are true and correct; and

(8) The maintenance application fee.

(d) Where no maintenance application is timely filed, a certificate of recordal will be designated inactive. However, such certificate may be designated active if the certificate holder files the prescribed maintenance fee and application and the additional surcharge within six months following the expiration of the certificate of recordal.

(e) After the six-month period following the expiration of the certificate of recordal, the certificate of recordal shall be deemed active only if the certificate holder files a new application for recordal with the prescribed fee for obtaining a fastener insignia and attaches a copy of the expired certificate of recordal.

(f) A separate maintenance application and fee must be filed and paid for each recorded insignia.

§ 280.721 Notification of changes of address.

The applicant or the holder of a certificate of recordal shall notify the Commissioner of any change of address or change of name no later than six months after the change. The holder must do so whether the certificate of recordal is in an active or inactive status.

§ 280.722 Transfer or amendment of the certificate of recordal.

(a) The certificate of recordal cannot be transferred or assigned.

(b) The certificate of recordal may be amended only to show a change of name or change of address.

§ 280.723 Transfer or assignment of the trademark registration or recorded insignia.

(a) A trademark application or registration which forms the basis of a fastener recordal may be transferred or assigned. Any transfer or assignment of such an application or registration

shall be recorded in the Patent and Trademark Office within three months of the transfer or assignment. A copy of such transfer or assignment must also be sent to: Box Fastener, Commissioner of Patents and Trademarks, Washington, DC 20231.

(b) Upon transfer or assignment of a trademark application or registration which forms the basis of a certificate of recordal, the Commissioner shall designate the certificate of recordal as inactive. The certificate of recordal shall be deemed inactive as of the effective date of the transfer or assignment. Certificates of recordal designated inactive due to transfer or assignment of a trademark application or registration cannot be reactivated.

(c) An assigned trademark application or registration may form the basis for a new application for recordal of a fastener insignia.

(d) A fastener insignia consisting of an alphanumeric designation issued by the Commissioner can be transferred or assigned.

(e) Upon transfer or assignment of an alphanumeric designation, the Commissioner shall designate such alphanumeric designation as inactive. The alphanumeric designation shall be deemed inactive as of the effective date of the transfer or assignment. Alphanumeric designations which are designated inactive due to transfer or assignment may be reactivated upon application by the assignee of such alphanumeric designation. Such application must meet all the requirements of §280.710 and must include a copy of the pertinent portions of the document assigning rights in the alphanumeric designation. Such application must be filed within six months of the date of assignment.

§280.724 Change in status of trademark registration or amendment of the trademark.

(a) The Commissioner shall designate the certificate of recordal as inactive, upon:

(1) Issuance of a final decision on appeal which refuses registration of the application which formed the basis for the certificate of recordal; or

(2) Abandonment of the application which formed the basis for the certificate of recordal; or

(3) Cancellation or expiration of the trademark registration which formed the basis of the certificate of recordal.

(b) Any amendment of the mark in a trademark application or registration which forms the basis for a certificate of recordal will result in such certificate of recordal being designated inactive. The certificate of recordal shall become inactive as of the date of the amendment of the trademark. A new application for recordal of the amended trademark application or registration may be submitted to the Commissioner at any time.

(c) Certificates of recordal designated inactive due to cancellation, expiration, abandonment or amendment of the trademark application or registration cannot be reactivated.

§280.725 Cumulative listing of recordal information.

The Commissioner shall maintain a record of the names, current addresses, and legal entities of all recorded manufacturers and private label distributors and their recorded insignia.

§280.726 Records and files of the Patent and Trademark Office.

The records relating to fastener insignia shall be open to public inspection. Copies of any such records may be obtained upon request and payment of the fee set by the Commissioner.

Subpart I—Special Rule for the Accreditation of Certain Fastener Manufacturing Facilities, Whose Implemented Fastener Quality Assurance Systems Meet Defined Requirements, as Laboratories

SOURCE: 63 FR 18275, Apr. 14, 1998, unless otherwise noted.

§280.800 Introduction.

(a) This special rule applies to those fastener manufacturers, employing a fastener quality assurance system (QAS) as defined in this part, who wish to seek accreditation of the particular manufacturing facility employing the

QAS as a laboratory within the meaning of the Act. This rule consists of this subpart, and subparts J, K and L of this part. The rule adopts the view that a fastener manufacturing facility is deemed to be an accredited laboratory for purposes of the Act and this part if such facility employs a fastener quality assurance system (QAS) that has been formally registered by a NIST-recognized quality systems Registrar. The rule applies only to facilities manufacturing fasteners; raw materials for fastener manufacture must be tested and certified by a laboratory listed on the Accredited Laboratory List. This Subpart sets out the full process that NIST requires for the accreditation of a fastener manufacturing facility employing a QAS in the United States: A fastener manufacturing facility employing a QAS (a ''Facility'') will be deemed to be an accredited laboratory if it is registered by a Quality Systems Registrar (a ''Registrar'') that in turn has been accredited by a Registrar Accreditation Body (an ''Accreditor'') that has been recognized by NIST. Subpart J provides for foreign Accreditors to be recognized and to recognize Registrars under the same procedures.

(b) A chain is thus established to assure the proper regulation of Facilities: NIST recognizes Accreditors that meet the requirements of subpart K of this part, which is based upon ISO Guide 61; the NIST-recognized Accreditors may in turn accredit Registrars that meet the requirements of subpart L of this part, which is based upon ISO Guide 62. The Registrars, in turn, may register Facilities that satisfy the elements of a fastener quality assurance system (QAS), as defined in this part.

(c) Within this subpart, §§ 280.801 through 280.809 contain the procedures that NIST uses to process requests from Accreditors for recognition by NIST. Section 280.810 establishes three lists that NIST will maintain: Section 280.810(a) provides for a list of Accreditors that have been recognized by NIST; § 280.810(b) provides for a list of Registrars that have been accredited by Accreditors listed according to § 280.810(a); and § 280.810(c) provides for a list of Facilities that have been registered by Registrars listed according to § 280.810(b). The remainder of this subpart, §§ 280.811 and 280.812, contain procedural provisions related to the lists established by § 280.810.

§ 280.801 Application.

(a) Application must be made by Accreditors to NIST for recognition to accredit Registrars under the Act. Upon request, NIST will provide application forms and instructions. The applicant shall complete the application in English and may provide whatever additional enclosures, attachments or exhibits the applicant deems appropriate.

(b) Application packages may be obtained from: Manager, FQA Accreditation Body Evaluation Program, NIST, Bldg. 820, Room 282, Gaithersburg, Maryland 20899. Requests may be made by mail or by FAX to: (301) 963–2871.

(c) The applicant shall reimburse NIST for all costs incurred in the evaluation of its accreditation program and subsequent costs incurred in ensuring the continued compliance of its program. Reimbursement shall be in accordance with the fee schedule established by NIST for this purpose.

(d) An application may be revised by an applicant at any time prior to the final decision by NIST. An application may be withdrawn by an applicant, without prejudice, at any time prior to the final decision by NIST.

§ 280.802 Review and decision process.

(a) Applications submitted by Accreditors will be accepted by NIST and their receipt acknowledged in writing. The applications will be reviewed by NIST against the criteria specified in this subpart and in subpart K of this part. NIST may request additional information as needed from the applicant.

(b) NIST shall conduct on-site assessments of the facilities of the applicant including all of the applicant's organizational units and locations covered by the application.

(c) If the applicant's program is deemed by NIST to have met the requirements for recognition, the applicant shall be notified by NIST in writing. The recognition notice shall include the date when the recognition begins and the scope of the recognition. The recognition period shall be for as

long as the Accreditor continues to satisfy the requirements of § 280.803. As part of maintaining its approved status, each Accreditor shall agree to be reassessed by NIST every two years following its initial notice of recognition. NIST will maintain and make available to the public a list of recognized Accreditors.

(d) If the applicant does not meet the requirements for recognition, the applicant shall be notified in writing, listing the specific requirements from this subpart and subpart K of this part which the applicant's program has not met. After receipt of such a notification, and within the response period provided by NIST, the applicant may:

(1) Submit additional information for further review. Reviewing the new submission may involve additional on-site visits by NIST personnel. Additional fees may be required. Or,

(2) Submit a request that the original application be reconsidered, including a statement of reasons why the applicant should have been recognized.

§ 280.803 Criteria for recognition.

An applicant for NIST recognition must demonstrate the ability to operate a registrar accreditation program consistent with the requirements of this subpart and subparts A and K of this part, and accredit registrars of Facilities to requirements set out in subpart L of this part.

§ 280.804 Maintaining recognized status.

(a) Accreditors shall continue to satisfy all the requirements of recognition during the recognition period.

(b) Upon request, recognized Accreditors shall make available to NIST and/or BXA all records and materials pertaining to the program.

(c) NIST has the right to participate as an observer during any on-site visit to a Registrar being audited by a NIST-recognized Accreditor, or a Facility being audited by an accredited Registrar, or it may perform its own surveillance visit of such bodies at its discretion.

(d) Neither the Accreditor, nor any Registrar it accredits, nor any Facility registered under the Act and this part shall take any action which states or implies the approval, or endorsement by NIST or any other agency of the U.S. Federal Government of any product or report pertaining to a product associated with any activities carried out under the recognition. None of these entities may take any action which states or implies that they are recognized or authorized by NIST to act or perform in any area(s) beyond that which was specified in their recognition under this part.

§ 280.805 Voluntary termination of recognition.

An Accreditor may voluntarily terminate its recognition by giving written notice to NIST and to all Registrars accredited by that body under its accreditation program. The written notice shall state the date on which the termination will take effect.

§ 280.806 Involuntary termination of recognition by NIST.

(a) NIST may terminate or suspend its recognition of an Accreditor if such an action is deemed to be in the public interest.

(b) Before terminating the recognition of an Accreditor, NIST will notify the Accreditor in writing, giving it the opportunity to rebut or correct the stated reasons for the proposed termination. If the problems are not corrected or reconciled within 30 days, or such longer time as NIST in its sole discretion may grant, the termination shall become effective.

(c) An Accreditor may appeal a termination to the Director by submitting a statement of reasons why the recognition should not be terminated. NIST may, at its discretion, hold in abeyance the termination action pending a final decision by the Director. Within 60 days following receipt of the appeal, the Director shall inform the Accreditor in writing of his or her decision.

(d) Registrars and registered organizations which have been listed by NIST in accordance with this Subpart, based on their accreditation by an Accreditor whose recognition has been terminated, shall be removed from the list, unless an exception is granted by NIST.

§ 280.807 Subcontracting.

If a recognized Accreditor, an accredited Registrar, or a registered Facility subcontracts any of its functions to another entity it must place the work with another recognized Accreditor, accredited Registrar, or registered Facility; inform the client, before the fact, that subcontracting will be necessary, and clearly indicate in all appropriate records, and reports to the client, specifically what functions were subcontracted.

§ 280.808 Reports.

Reports and records shall be maintained in such a manner to preserve original data, and be collected as required into a final form, sufficient to satisfy customer and legal requirements. Such reports shall be provided upon request to the Bureau of Export Administration, to the National Institute of Standards and Technology, or to any other agency of the federal government authorized to obtain such records under this part.

§ 280.809 Recordkeeping.

Each recognized Accreditor, accredited Registrar, or fastener manufacturer whose Facility has been registered shall retain all applicable records required under the Act and this part for 5 years. All records are subject to the requirements in § 280.7 of this part.

§ 280.810 Listing of recognized accreditors, accredited registrars, and registered facilities.

(a) *List of Accreditors.* NIST shall prepare and maintain a list of Accreditors recognized under this subpart and subpart J of this part.

(b) *List of Registrars.* NIST shall prepare and maintain a list of Registrars accredited by Accreditors listed in accordance with § 280.810(a).

(1) Names and information regarding accredited Registrars may only be included on the list from information submitted to NIST by an Accreditor listed in accordance with § 280.810(a) that submits the listing fee established by NIST and the following information, in English:

(i) The name of the Accreditor which granted the accreditation;

(ii) The name and address of the Registrar affected by the accreditation action;

(iii) The nature of the accreditation action (e.g., initial accreditation, renewal of accreditation, etc.);

(iv) A copy of the Registrar's accreditation certificate and a scope of accreditation which states the quality system standard(s) for which the Registrar has been accredited for purposes of assessing and registering a fastener manufacturer's Facility; and

(v) The name and telephone number of the accredited Registrar's authorized representative(s), and information concerning the physical locations of all organizational units involved in the accreditation activities.

(2) All Accreditors listed by NIST in accordance with § 280.810(a) shall promptly notify NIST of each accreditation action taken. Accreditation actions include initial accreditations, denials of accreditation, renewals, suspensions, terminations, and changes in scope. Notifications shall be filed with: Fastener Quality Act Program Manager, Office of Standards Services, National Institute of Standards and Technology, Gaithersburg, Maryland 20899.

(c) *List of Facilities.* NIST shall prepare and maintain a list of Facilities registered by Registrars listed in accordance with § 280.810(b).

(1) Names and information regarding registered Facilities may only be included on the list from information submitted to NIST by accredited Registrars listed in accordance with § 280.810(b) that submit the listing fee established by NIST, through their Accreditors, and the following information:

(i) The name of the fastener manufacturer and the address of the registered Facility;

(ii) The name of the authorized representative of the fastener manufacturer whose Facility is registered;

(iii) The scope of the registration, stating the quality system standard(s) to which the Facility has been registered; and

(iv) The effective dates of the registration.

(2) All Registrars listed by NIST in accordance with § 280.810(b) shall

promptly notify NIST of each registration action. Registration actions include initial registrations, denials of registration, renewals, suspensions, terminations, and changes in scope. Notifications shall be filed with: Fastener Quality Act Program Manager, Office of Standards Services, National Institute of Standards and Technology, Gaithersburg, Maryland 20899.

(3)(i) If a Facility intends to be listed in accordance with paragraph (c)(1) of this section but the registration process will not be completed by June 1, 1999, the Facility may be provisionally listed on the Facilities List by providing the following to NIST on or before September 30, 1998:

(A) Certification that:

(*1*) The Facility is registered to QS–9000 or an equivalent by a quality systems registrar;

(*2*) The facility conforms to all other requirements of the Act and these regulations at the time of certification;

(*3*) If the Facility ceases to be registered to QS–9000 or an equivalent by an accredited Registrar and/or ceases to conform to any other requirement of the Act and these regulations at any time during the provisional listing period, it will notify NIST of that fact within three working days; and

(*4*) If the Facility fails to apply to an accredited Registrar for registration under the FQA within 30 days of the time the Registrar is accredited by a NIST-approved Accreditor, an authorized representative of the Facility will immediately notify NIST. (If the Facility's current Registrar decides not to seek accreditaton under the FQA, it is the Facility's responsibility to apply to another Registrar that has been approved by NIST-ABEP.);

(B) A list of fasteners produced or processed by the Facility, identified by either a part number or a specification number;

(C) A list of standards included in the Facility's registration;

(D) A copy of the Facility's registration certificate; and

(E) The listing fee established by NIST.

(ii) The Facility must meet all the requirements of the Act and these regulations by May 25, 1999. If the Facility fails to receive FQA registration by May 25, 1999, it will be removed from the Facilities List.

(d) These lists will be readily accessible to the public. Only entities listed by NIST are authorized to offer services which comply with the Act and this part. NIST shall revise as appropriate all listings when notified of applicable actions and shall take appropriate steps to make changes promptly available to the public.

[63 FR 18275, Apr. 14, 1998, as amended at 63 FR 35508, June 30, 1998; 63 FR 37170, July 9, 1998; 63 FR 51526, Sept. 28, 1998]

§ 280.811 Removal from a list.

NIST may remove from a list any listed entity if NIST deems such action to be in the public interest. An entity may appeal the removal or proposed removal from a list to the Director by submitting a statement of reasons why it should remain on the list. NIST may, at its discretion, hold in abeyance a removal action pending a final decision by the Director. The Director shall inform the entity in writing of the decision within sixty days following receipt of the appeal.

§ 280.812 Appeal.

An applicant Accreditor, Registrar, or fastener manufacturer whose Facility has been registered may appeal the removal or proposed removal from the Accreditors list, the Registrars list, or the Facilities list, to the Director.

Subpart J—Recognition of Foreign Registrar Accreditation Bodies

SOURCE: 63 FR 18277, Apr. 14, 1998, unless otherwise noted.

§ 280.900 Introduction.

In accordance with section 6(a)(1)(C) of the Act, this subpart sets forth the conditions under which the recognition of foreign entities by their governments, by organizations acting on behalf of their governments, or by organizations recognized by the Director shall be deemed to meet the requirements of the Act.

§ 280.901 Recognition of foreign entities.

Foreign Accreditors wishing to be recognized to accredit Registrars must submit an application for evaluation to NIST according to subpart I of this part. NIST recognition is limited to bodies that accredit Registrars which register Facilities producing fasteners covered by the Act. To be recognized by NIST, Accreditors must meet conditions set out in subparts I and K of this part and accredit Registrars of Facilities to conditions set out in subpart L of this part.

Subpart K—Requirements for Registrar Accreditation Bodies (Accreditors)

SOURCE: 63 FR 18278, Apr. 14, 1998, unless otherwise noted.

GENERAL

§ 280.1000 Introduction.

This subpart sets out organizational, operational and other requirements that must be met by all Accreditors recognized by NIST under subpart I or J of this part. This subpart also sets out the requirements against which an Accreditor assesses the competence of an applicant Registrar.

§ 280.1001 Scope.

These are general requirements for an Accreditor to follow if it is to be recognized as competent and reliable in assessing and subsequently accrediting Registrars.

REQUIREMENTS FOR ACCREDITORS

§ 280.1010 Accreditors.

(a) *General provisions.* (1) The policies and procedures under which the Accreditor operates shall be non-discriminatory, and they shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicant bodies other than as specified in this part.

(2) The Accreditor shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the applicant body or membership of any association or group, nor shall accreditation be conditional upon the number of bodies already accredited.

(3) The accreditation criteria against which the competence of a Registrar is assessed shall be those outlined in subpart L of this part. If an explanation is required as to the application of these documents to a specific accreditation program, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the Accreditor.

(4) The Accreditor shall confine its requirements, assessment and decisions on accreditation to those matters specifically related to the scope of the accreditation being considered.

(b) *Organization of a recognized Accreditor.* The structure of the Accreditor shall be such as to give confidence in its accreditations. In particular, the Accreditor shall:

(1) Be impartial;

(2) Be responsible for its decisions relating to the granting, maintaining; extending, reducing, suspending and withdrawing of accreditation;

(3) Identify the management (committee, group or person) which will have overall responsibility for all of the following:

(i) Performance of assessment and accreditation as defined in this part;

(ii) Formulation of policy matters relating to the operation of the Accreditor;

(iii) Decisions on accreditation;

(iv) Supervision of the implementation of its policies;

(v) Supervision of the finance of the Accreditor; and

(vi) Delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;

(4) Have documents which demonstrate that it is a legal entity;

(5) Have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the Accreditor; this structure shall enable

the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the accreditation system;

(6) Ensure that each decision on accreditation is taken by a person or persons different from those who carried out the assessment;

(7) Have rights and responsibilities relevant to its accreditation activities;

(8) Have adequate arrangements to cover liabilities arising from its operations and/or activities;

(9) Have financial stability and resources required for the operation of an accreditation system;

(10) Employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing accreditation functions relating to the type, range and volume of work performed, under a responsible senior executive;

(11) Have a quality system, as outlined in paragraph (d) of this section, giving confidence in its ability to operate an accreditation system for registration bodies;

(12) Have policies and procedures that distinguish between accreditation and any other activities in which the Accreditor is engaged;

(13) Together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;

(14) Have formal rules and structure for the appointment and operation of any committees which are involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions;

(15) Ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditations and shall not offer or provide, directly or indirectly, those services that accredit others to perform, consulting services to obtain or maintain accreditation, or services to design, implement or maintain a certification scheme;

(16) Have policies and procedures for the resolution of complaints, appeals and disputes received from bodies or other parties about the handling of accreditation of any related matters;

(17) Have a structure where members are chosen to provide a balance of interest, where no single interest predominates; and

(18) Assure that other products, processes or services that may be offered, directly or indirectly, do not compromise confidentiality or the objectivity or impartiality of its accreditation process and decisions.

(c) *Subcontracting.* (1) When an Accreditor decides to subcontract work related to accreditation (e.g. audits) to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflict of interest, shall be drawn up. The Accreditor shall:

(i) Take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending or withdrawing accreditation;

(ii) Ensure that the subcontracted body or person is competent and complies with the applicable provisions of this part, including section 280.807, and is not involved, either directly or through its employer, with the design, implementation or maintenance of a registration scheme in such a way that impartiality could be compromised; and

(iii) Obtain the consent of the applicant or accredited body.

(2) Requirements in paragraphs (c)(1)(i) and (ii) of this section are also relevant, by extension, when an Accreditor uses, for granting its own accreditation, work provided by another Accreditor with which it has signed an agreement.

(d) *Quality system.* (1) The management of the Accreditor with executive responsibility for quality shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

(2) The Accreditor shall operate a quality system in accordance with the relevant elements of this part and appropriate to the type, range and volume of work performed. This quality system shall be documented, and the

documentation shall be available for use by the staff of the Accreditor.

(3) The Accreditor shall ensure effective implementation of the documented quality system procedures and instructions.

(4) The Accreditor shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to ensure that a quality system is established, implemented and maintained in accordance with this part, and report on the performance of the quality system to the management of the Accreditor for review and as a basis for improvement of the quality system.

(5) The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following:

(i) A quality policy statement;

(ii) A brief description of the legal status of the Accreditor, including the names of its owners, if applicable, and, if different, the names of the persons who control it;

(iii) The names, qualifications, experience and terms of reference of the senior executive and other accreditation personnel influencing the quality of the accreditation functions;

(iv) An organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those making decisions regarding accreditation;

(v) A description of the organization of the Accreditor, including details of the management (committee, group or person), its constitution, terms of reference and rules of procedure;

(vi) The policy and procedures for conducting management reviews;

(vii) Administrative procedures including document control;

(viii) The operational and functional duties and service pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;

(ix) The policy and procedures for the recruitment and training of Accreditor personnel (including auditors) and monitoring their performance;

(x) A list of its subcontractors and details of the procedures for assessing, recording and monitoring their competence;

(xi) Its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;

(xii) The policy and procedures for implementing the accreditation process, including:

(A) The conditions for issue, retention and withdrawal of accreditation documents;

(B) Checks of the use and application of documents used in the accreditation;

(C) The procedures for assessing and accrediting applicants; and

(D) The procedures for surveillance and reassessment of accredited bodies.

(xiii) The policy and procedures for dealing with appeals, complaints and disputes; and

(xiv) The procedures for conducting internal audits based on appropriate international documentation.

(e) *Conditions for granting, maintaining, extending, reducing, suspending and withdrawing accreditation.* (1) The Accreditor shall specify the conditions for granting, maintaining, extending and reducing accreditation, and the conditions under which accreditation may be suspended or withdrawn, partially or in total, for all or part of the accredited body's scope of accreditation. In particular, the Accreditor shall require the accredited body to notify it promptly of any intended changes to the quality system or other changes which may affect conformity.

(2) The Accreditor shall have procedures to grant, maintain, withdraw and suspend accreditation; to extend or reduce the scope of accreditation; and to conduct reassessment in the event of changes significantly affecting the activity and operation of the accredited body (such as change of ownership, changes in personnel or equipment), or if analysis of a complaint or any other information indicates that the accredited body no longer complies with the requirements of the Accreditor.

(f) *Internal audits and management reviews.* (1) The Accreditor shall conduct periodic internal audits covering all

procedures in a planned and systematic manner, to verify that the quality system is being implemented and is effective. The Accreditor shall ensure that personnel responsible for the area audited are informed of the outcome of the audit; corrective action is taken in a timely and appropriate manner; and the results of the audit are documented.

(2) The top management of the Accreditor shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this part and the stated quality policy and objectives. Records of such reviews shall be maintained.

(g) *Documentation.* (1) The Accreditor shall document, update at regular intervals, and make available (through publications, electronic media or other means), on request:

(i) Information about the authority under which the Accreditor operates;

(ii) A documented statement of its accreditation system, including its rules and procedures for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;

(iii) Information about the assessment and accreditation process;

(iv) A description of the means by which the Accreditor obtains financial support, and general information on the fees charged to applicants and accredited bodies;

(v) A description of the rights and duties of applicants and accredited bodies, as specified, including requirements, restrictions or limitations on the use of the Accreditor's logo and on the ways of referring to the accreditation granted, in conformance with §280.804(d); and

(vi) Information on procedures for handling complaints, describing the scope of accreditation granted to each.

(2) The Accreditor shall establish and maintain procedures to control all documents and data that relate to its accreditation functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the Accreditor, or applicants and accredited bodies, when required to perform any function relating to the activities of applicants and accredited bodies.

(h) *Records.* (1) The Accreditor shall maintain a record system to suit its particular circumstances and to comply with this part. The records shall demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and other documents relating to granting, maintaining, extending, reducing, suspending or withdrawing accreditation. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and confidentiality of the information. The records shall be kept for a period of five years.

(2) The Accreditor shall have a policy and procedures for retaining records for a period of five years. The Accreditor shall have a policy and procedures concerning access to these records consistent with paragraph (h)(1) of this section.

(i) *Confidentiality.* (1) The Accreditor shall have adequate arrangements, consistent with applicable laws, to safeguard confidentiality of the information obtained in the course of its accreditation activities at all levels of its organization, including committees and external bodies or individuals acting on its behalf.

(2) Except as required in this part, information about a particular body shall not be disclosed to a third party without the written consent of the body.

[63 FR 18278, Apr. 14, 1998; 63 FR 34965, June 26, 1998]

§280.1011 Accreditor personnel.

(a) *General provisions.* (1) The personnel of the Accreditor involved in accreditation shall be competent for the functions they perform.

(2) Information on the relevant qualifications, training and experience of

each member of the personnel involved in the accreditation process shall be maintained by the Accreditor. Records of training and experience shall be kept up to date.

(3) Clearly documented instructions shall be available to the personnel describing their duties and responsibilities. These instructions shall be maintained up to date.

(b) *Qualification criteria for auditors and technical experts.* (1) In order to ensure that assessments are carried out effectively and uniformly, the minimum relevant criteria for competence shall be defined by the Accreditor.

(2) Auditors shall meet the requirements of the appropriate international documentation.

(3) Technical experts are not required to comply with the requirements for auditors, and guidance on their personal attributes may be obtained from appropriate international documentation.

(c) *Selection procedure.* (1) The Accreditor shall have a procedure for selecting auditors and, if applicable, technical experts on the basis of their competence, training, qualifications and experience, and for initially assessing the conduct of auditors and technical experts during assessments, and subsequently monitoring the performance of auditors and technical experts.

(2) When selecting the audit team to be appointed for a specific assessment, the Accreditor shall ensure that the skills brought to each assignment are appropriate. The team shall:

(i) Be familiar with the Act and this part, accreditation procedures and accreditation requirements;

(ii) Have a thorough knowledge of the relevant assessment method and assessment documents;

(iii) Have appropriate technical knowledge of the fastener technology for which accreditation is sought and, where relevant with associated procedures and their potential for failure (technical experts who are not auditors may fulfill this function);

(iv) Have a degree of understanding sufficient to make a reliable assessment of the competence of the accredited body to operate within its scope;

(v) Be able to communicate effectively, both in writing and orally, in the required languages.

(vi) Be free from any interest that might cause team members to act in other than an impartial or non-discriminatory manner, for example,

(A) Audit team members or their organization shall not have provided consulting services to the applicant or accredited body which compromise the accreditation process and decision; and

(B) In accordance with the directives of the Accreditor, the audit team members shall inform the Accreditor, prior to the assessment, about any existing, former or envisaged link between themselves or their organization and the body to be assessed.

(d) *Contracting of assessment personnel.* The Accreditor shall require the personnel involved in the assessment to sign a contract or other document by which they commit themselves to comply with the rules defined by the Accreditor, including those relating to confidentiality and those relating to independence from commercial and other interest, and any prior and/or present link with the bodies to be assessed. The Accreditor shall ensure that, and document how, any subcontracted assessment personnel satisfy all the requirements for personnel outlined in this subpart.

(e) *Assessment personnel records.* (1) The Accreditor shall possess and maintain up-to-date records on personnel conducting assessments, consisting of:

(i) Name and address;

(ii) Affiliation and position held in the organization;

(iii) Educational qualifications and professional status;

(iv) Experience and training in each field of competence of the Accreditor;

(v) Date of most recent updating of record; and

(vi) Performance appraisal.

(2) The Accreditor shall ensure, and verify, that any subcontracted body maintains records, which satisfy the requirements of this part, of assessment personnel who are subcontracted to the Accreditor.

(f) *Procedures for assessment teams.* Assessment teams shall be provided with up-to-date assessment instructions and

all relevant information on accreditation arrangements and procedures.

[63 FR 18278, Apr. 14, 1998; 63 FR 34965, June 26, 1998]

§ 280.1012 Decision on accreditation.

(a) The decision whether or not to accredit a body shall be made on the basis of the information gathered during the accreditation process and any other relevant information. Those who make the accreditation decision shall not have participated in the audit.

(b) The Accreditor shall not delegate authority for granting, maintaining, extending, reducing, suspending or withdrawing accreditation to an outside person or body.

(c) The Accreditor shall provide to each of its accredited bodies accreditation documents such as a letter outlining the scope of accreditation and a certificate signed by an officer who has been assigned such responsibility. These accreditation documents shall identify, for the body and each of its sites covered by the accreditation:

(1) The name and address;

(2) The scope of the accreditation granted, including as appropriate:

(i) The type of registration scheme;

(ii) The standards and/or other normative documents and regulatory requirements against which products, services or systems are registered; and

(iii) Fasteners covered by the Act.

(3) The effective date of accreditation and, as applicable, the term for which the accreditation is valid.

(d) In response to an application for an amendment to the scope of an accreditation already granted, the Accreditor shall decide what, if any, assessment procedure is appropriate to determine whether or not the amendment should be granted and shall act accordingly.

§ 280.1013 References to accredited status.

(a) An Accreditor which is proprietor or licensee of a symbol or logo, intended for use under its accreditation program, shall have a policy governing its use. It shall normally allow an accredited body to refer to its accreditation in certificates, reports, and stationery and publicity material relating to accredited activities.

(b) The Accreditor shall not allow use of its mark or logo in any way which implies that the Accreditor itself approved a product, service or system registered by an accredited body. Where a Facility is registered only with respect to its quality assurance system, the symbol or logo shall not be used on a product or in any other way that may be interpreted as denoting product conformance, as required by § 280.804(d).

(c) The Accreditor shall take suitable action to deal with incorrect reference to the accreditation system, or misleading use of accreditation logos found in advertisements, catalogues, etc. Such action could include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.

§ 280.1014 Change in the accreditation.

The Accreditor shall give due notice of any changes it intends to make in its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each accredited Registrar carries out any necessary adjustments to its procedures within such time as, in the opinion of the Accreditor, is reasonable.

§ 280.1015 Appeals, complaints and disputes.

The Accreditor shall keep a record of all appeals, complaints and disputes, and remedial actions relative to accreditation; take appropriate corrective and preventive action; and document the actions taken and assess their effectiveness.

§ 280.1016 Access to records of appeals, complaints and disputes.

The Accreditor shall require each applicant and accredited Registrar to make available to it, when requested, the records of all complaints, appeals and disputes, and subsequent actions.

REQUIREMENTS FOR ASSESSMENT

§ 280.1020 Application for accreditation.

(a)(1) As specified in § 280.1010(g)(1) of this part, the Accreditor shall maintain up-to-date detailed descriptions of the assessment and accreditation procedure, the documents containing the requirements for accreditation, and documents describing the rights and duties of accredited Registrars, and shall provide them to applicants and accredited Registrars. The Accreditor shall require that an accredited Registrar.

(i) Always complies with the relevant provisions of this part;

(ii) Makes all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, records (including internal audit reports) and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints;

(iii) Only claims that it is accredited with respect to those activities for which it has been granted accreditation;

(iv) Does not use its accreditation in such a manner as to bring the Accreditor into disrepute, and does not make any statement regarding its accreditation which the Accreditor may consider misleading or unauthorized;

(v) Upon suspension or withdrawal of its accreditation, discontinues use of all advertising matter that contains any reference thereto and returns any accreditation documents as required by the Accreditor;

(vi) Does not allow the fact of its accreditation to be used to imply that a product, process, system, or person is approved by the Accreditor, as required by § 280.804(d);

(vii) Ensures that no accreditation document, mark or report, or any part thereof, is used in a misleading manner; and

(viii) In making reference to its accreditation status in communication media such as documents, brochures or advertising, complies with the requirements of the Accreditor.

(2) When the desired scope of accreditation is related to a specific program any necessary explanation shall be provided to the applicant. If requested, additional application information shall be provided to the body.

(b) The Accreditor shall require an official application form, duly completed and signed by a duly authorized representative of the applicant, in which or attached to which:

(1) The scope of the desired accreditation is defined; and

(2) The applicant agrees to comply with the requirements for accreditation and to supply any information needed for its evaluation.

(c) At least the following shall be provided by the applicant prior to the on-site assessment:

(1) The general features of the applicant body, such as corporate entity, name, address, legal status and, where relevant, human and technical resources;

(2) General information concerning the body covered by the application, such as its functions, and its relationship in a larger corporate entity, and its physical locations;

(3) A description of the systems or products it registers and the standards or other normative documents applicable to each; and

(4) A copy of its quality manual and, where required, the associated documentation.

§ 280.1021 Preparation for assessment.

(a) Before proceeding with the assessment, the Accreditor shall conduct, and maintain records of, a review of the request for accreditation to ensure that:

(1) The requirements for accreditation are clearly defined and documented;

(2) Any difference in understanding between the Accreditor and the applicant is resolved; and

(3) The Accreditor has the capability to perform the accreditation service with respect to the scope of the accreditation sought, the location of the applicant's operations, and any special requirements such as the language used by the applicant.

(b) The Accreditor shall prepare a plan for its assessment activities to allow for the necessary arrangements to be made.

(c) The Accreditor shall nominate a qualified audit team to evaluate all material collected from the applicant and to conduct the audit on its behalf. Experts in the areas to be assessed may be attached to the Accreditor's team as advisers.

(d) The applicant shall be informed of the names of the members of the audit team who will carry out the assessment, with sufficient notice to appeal against the appointment of any particular auditors or experts.

(e) The audit team shall be formally appointed and provided with the appropriate working documents. The plan for and the date of the audit shall be agreed upon with the applicant. The mandate given to the audit team shall be clearly defined and made known to the applicant, and shall require the audit team to examine the structure, policies and procedures of the applicant, and confirm that these meet all the requirements relevant to the scope of accreditation, and that the procedures are implemented and are such as to give confidence in the registrations of the applicant.

§ 280.1022 Assessment.

(a) The audit team shall assess all services of the applicant covered by the defined scope against all applicable accreditation requirements.

(b) The Accreditor shall witness fully the on-site activities of one or more assessments or audits conducted by an applicant before an initial accreditation is granted for any function requiring on-site activity by the applicant.

§ 280.1023 Assessment report.

(a) The Accreditor may adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that:

(1) A meeting takes place between the audit team and the applicant's management prior to leaving the premises, at which the audit team provides a written or oral indication on the conformity of the applicant with the particular accreditation requirements and provides an opportunity for the applicant to ask questions about the findings and their basis;

(2) The audit team provides the Accreditor with a report of its findings as to the applicant's conformity to all of the accreditation requirements;

(3) A report on the outcome of the assessment is promptly brought to the applicant's attention by the Accreditor, identifying any nonconformity to be discharged in order to comply with all of the accreditation requirements;

(4) The Accreditor shall invite the applicant to comment on the report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any nonconformity with the accreditation requirements identified during the assessment, and shall inform the applicant of the need for full or partial reassessment or whether a written declaration to be confirmed during surveillance will be considered adequate;

(5) The report shall contain as a minimum:

(i) The date(s) of the audit(s);

(ii) The name(s) of the person(s) responsible for the report;

(iii) The names and addresses of all sites audited;

(iv) The assessed scope of accreditation or reference thereto;

(v) Comments on the conformity of the applicant with the accreditation requirements and, where applicable, any useful comparisons with the results of previous assessment of the applicant; and

(vi) An explanation of any differences from the information presented to the applicant at the closing meeting.

(b) If the final report authorized by the Accreditor differs from the report referred to in paragraphs (b) (3) and (5) of this section, it shall be submitted to the applicant with an explanation of any differences from the previous report. The report shall take into consideration:

(1) The qualification, experience and authority of the staff encountered;

(2) The adequacy of the internal organization and procedures adopted by the applicant to give confidence in the quality of its services; and

(3) The actions taken to correct identified nonconformities including, where applicable, those identified at previous assessments.

§ 280.1024 Surveillance and reassessment procedures.

(a) The Accreditor shall have an established documented program, consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to verify that its accredited Registrar continues to comply with the accreditation requirements.

(b) Surveillance and reassessment procedures shall be consistent with those concerning the assessment of the applicant as described in this part.

(c)(1) The Accreditor shall have arrangements to ensure that an accredited Registrar informs it without delay of changes in any aspects of its status or operation that affect its:

(i) Legal, commercial or organizational status;

(ii) Organization and management, for example key managerial staff;

(iii) Policies or procedures, where appropriate;

(iv) Premises; and

(v) Personnel, equipment, facilities, working environment or other resources, where significant.

(2) The accredited Registrar shall also inform the Accreditor of other such matters that may affect activities, or conformance with the requirements, or any other relevant criteria of competence specified by the Accreditor.

Subpart L—Requirements for Registrars

SOURCE: 63 FR 18282, Apr. 14, 1998, unless otherwise noted.

GENERAL

§ 280.1100 Introduction.

This subpart sets out organizational, operational and other requirements that must be met by all Registrars accredited under subparts I or J of this part.

§ 280.1101 Scope.

These are general requirements that must be met by a third-party body registering Facilities.

NOTE: In some countries, the bodies which verify conformity of quality systems to specified standards are called ''certification bodies,'' in others ''registration bodies,'' in others ''assessment and registration bodies'' or ''certification/registration bodies,'' and in still others ''registrars.'' Reference to such bodies as ''Registrars'' should not be understood to be limiting.

REQUIREMENTS FOR REGISTRARS

§ 280.1110 Registrars.

(a) *General provisions.* (1) The policies and procedures under which the Registrar operates shall be non-discriminatory, and they shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicants other than as specified in this part.

(2) The Registrar shall make its services accessible to all applicants. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the applicant body or membership of any association or group, nor shall registration be conditional upon the number of Facilities already registered.

(3) The criteria against which the quality assurance system of an applicant is assessed shall be those outlined in the quality system standards or other normative documents relevant to the function performed. If an explanation is required as to the application of these documents to a specific registration program, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the Registrar.

(4) The Registrar shall confine its requirements, assessment, and decision on registration to those matters specifically related to the scope of the registration being considered.

(b) *Organization of a registrar.* The structure of the Registrar shall be such as to give confidence in its registrations. In particular, the Registrar shall:

(1) Be impartial;

(2) Be responsible for its decisions relating to the granting, maintaining, extending, reducing, suspending and withdrawing of registration;

(3) Identify the management (committee, group, or person) which will have overall responsibility for each of the following:

(i) Performance of assessment and registration as defined in this part;

(ii) Formulation of policy matters relating to the operation of the Registrar,

(iii) Decisions on registration;

(iv) Supervision of the implementation of its policies;

(v) Supervision of the finances of the Registrar; and

(vi) Delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf.

(4) Have documents which demonstrate that it is a legal entity;

(5) Have a documented structure which safeguards impartiality, including provisions to assure the impartiality of the operations of the Registrar, this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the registration system;

(6) Ensure that each decision on registration is taken by a person or persons different from those who carried out the assessment;

(7) Have rights and responsibilities relevant to its registration activities;

(8) Have adequate arrangements to cover liabilities arising from its operations and/or activities;

(9) Have the financial stability and resources required for the operation of a registration system;

(10) Employ a sufficient number of personnel having the necessary education, training, technical knowledge, and experience for performing registration functions relating to the type, range, and volume of work performed, under a responsible senior executive;

(11) Have a quality system, as outlined in paragraph (d) of this section, giving confidence in its ability to operate a registration system for Facilities;

(12) Have policies and procedures that distinguish between registration and any other activities in which the Registrar is engaged;

(13) Together with its senior executive and staff, be free from any commercial, financial, and other pressures which might influence the results of the registration process;

(14) Have formal rules and structures for the appointment and operation of any committees which are involved in the registration process; such committees shall be free from any commercial, financial, and other pressure that might influence decisions;

(15) Ensure that activities of related bodies do not affect the confidentiality, objectivity, or impartiality of its registrations and shall not offer or provide, directly or indirectly, those services that it registers others to perform, consulting services to obtain or maintain registration, or services to design, implement, or maintain quality systems;

(16) Have policies and procedures for the resolution of complaints, appeals, and disputes received from fastener manufacturers or other parties about the handling of registration or any other related matters;

(17) Have a structure where members are chosen to provide a balance of interests, where no single interest predominates; and

(18) Assure that the other products, processes, or services that may be offered, directly or indirectly, do not compromise confidentiality or the objectivity or impartiality of its registration process and decisions.

(c) *Subcontracting.* (1) When a Registrar decides to subcontract work related to registration (e.g. audits) to an external body or person, a properly documented agreement covering the arrangements, including confidentiality and conflicts of interest, shall be drawn up. The Registrar shall:

(i) Take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, reducing, suspending, or withdrawing registration;

(ii) Ensure that the subcontracted body or person is competent and complies with the applicable provisions of this part, including §280.7, and is not involved, either directly or through its employer, with the design, implementation, or maintenance of a quality system in such a way that impartiality could be compromised; and

(iii) Obtain the consent of the applicant or fastener manufacturer whose Facility is registered.

(2) Requirements in paragraphs (c) (1) and (2) of this section are also relevant, by extension, when a Registrar uses, for granting its own registration, work provided by another Registrar with which it has signed an agreement.

(d) *Quality system.* (1) The management of the Registrar with executive responsibility for quality shall define and document its policy for quality, including objectives for quality and its commitment to quality. The management shall ensure that this policy is understood, implemented, and maintained at all levels of the organization.

(2) The Registrar shall operate a quality system in accordance with the relevant elements of this part and appropriate to the type, range, and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the staff of the Registrar.

(3) The Registrar shall ensure effective implementation of the documented quality system procedures and instructions.

(4) The Registrar shall designate a person with direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority to ensure that a quality system is established, implemented, and maintained in accordance with this part, and report on the performance of the quality system to the management of the Registrar for review and as a basis for improvement of the quality system.

(5) The quality system shall be documented in a quality manual and associated quality procedures and the quality manual shall contain or refer to at least the following:

(i) A quality policy statement;

(ii) A brief description of the legal status of the Registrar, including the names of its owners, if applicable, and, if different, the names of the persons who control it;

(iii) The names and qualifications, experience, and terms of reference of the senior executive and other certification/registration personnel, affecting the quality of the certification/registration function;

(iv) An organization chart showing lines of authority, responsibility, and allocation of functions stemming from the senior executive and, in particular, the relationship between those responsible for the assessment and those taking decisions regarding registration;

(v) A description of the organization of the registration body, including details of the management (committee, group, or person), its constitution, terms of reference and rules of procedure;

(vi) The policy and procedures for conducting management reviews;

(vii) Administrative procedures including document control;

(viii) The operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;

(ix) The policy and procedures for the recruitment and training of registration body personnel (including auditors) and monitoring their performance;

(x) A list of its subcontractors and details of the procedure for assessing, recording, and monitoring their competence;

(xi) Its procedures for handling nonconformities and for assuring the effectiveness of any corrective actions taken;

(xii) The policy and procedures for implementing the registration process, including:

(A) The conditions for issue, retention, and withdrawal of registration documents;

(B) Checks of the use and application of documents used in the registration of quality systems;

(C) The procedures for assessing and registering fastener manufacturers' quality systems as employed in particular Facilities; and

(D) The procedures for surveillance and reassessment of registered Facilities.

(xiii) The policy and procedures for dealing with appeals, complaints, and disputes; and

(xiv) The procedures for conducting internal audits based on the provisions described in appropriate international documentation.

(e) *Conditions for granting, maintaining, extending, reducing, suspending, and withdrawing registration.* (1) The Registrar shall specify the conditions for

granting, maintaining, reducing, and extending registration and the conditions under which registration may be suspended or withdrawn, partially or in total, for all or part of the Facility's scope of registration. In particular, the Registrar shall require the fastener manufacturer to notify it promptly of any intended changes to the quality assurance system or other changes which may affect conformity.

(2) The Registrar shall require the fastener manufacturer to have a documented quality system which conforms to applicable quality system standards or other normative documents.

(3) The Registrar shall have procedures to grant, maintain, withdraw and, if applicable, suspend registration; to extend or reduce the scope of registration; and to conduct reassessment in the event of changes significantly affecting the activity and operation of the Facility (such as change of ownership, changes in personnel or equipment), or if analysis of a complaint or any other information indicates that the registered fastener Facility no longer complies with the requirements of the Registrar.

(4) The Registrar shall have documented procedures which shall be made available on request for:

(i) Initial assessment and for the surveillance and reassessment of a fastener manufacturer's quality assurance system as employed in a particular Facility;

(ii) Continuing conformity with relevant requirements; and for verifying and recording that a fastener manufacturer takes corrective action on a timely basis to correct all nonconformities; and

(iii) Identifying and recording nonconformities and the need for corrective action by fastener manufacturers on a timely basis for such items as incorrect references to the registration or misleading use of registration information.

(f) *Internal audits and management reviews.* (1) The Registrar shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality assurance system is implemented and is effective. The Registrar shall ensure that personnel responsible for the area audited are informed of the outcome of the audit; corrective action is taken in a timely and appropriate manner; and the results of the audit are recorded.

(2) The top management of the Registrar shall review its quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this part and the stated quality policy and objectives. Records of such reviews shall be maintained.

(g) *Documentation.* (1) The Registrar shall document, update at regular intervals, and make available through publications, electronic media, or other means), on request;

(i) Information about the authority under which the Registrar operates;

(ii) A documented statement of its registration system including its rules and procedures for granting, maintaining, extending, reducing, suspending, and withdrawing registration;

(iii) Information about the assessment and registration process;

(iv) A description of the means by which the Registrar obtains financial support, and general information on the fees charged to applicants and fastener manufacturers whose Facilities have been registered;

(v) A description of the rights and duties of applicants and fastener manufacturers whose Facilities have been registered, including requirements, restrictions, or limitations on the use of the Registrar's logo and on the ways of referring to the registration granted;

(vi) Information on procedures for handling complaints, appeals and disputes; and

(vii) A directory of registered Facilities, including their locations, describing the scope of registration granted to each.

(2) The Registrar shall establish and maintain procedures to control all documents and data that relate to its registration functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status

identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the Registrar or of the fastener manufacturer whose Facility is registered, when required to perform any function relating to the activities of an applicant or registered Facility.

(h) *Records.* (1) The Registrar shall maintain a record system to suit its particular circumstances and to comply with this part. The records shall demonstrate that the registration procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and other documents relating to granting, maintaining, extending, reducing, suspending, or withdrawing registration. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and confidentiality of the information. The records shall be kept for a period of five years.

(2) The Registrar shall have a policy and procedures for retaining records for a period of five years. The Registrar shall have a policy and procedures concerning access to these records consistent with paragraph (h)(1) of this section.

(i) *Confidentiality.* (1) The Registrar shall have adequate arrangements, consistent with applicable laws to safeguard confidentiality of the information obtained in the course of its registration activities at all levels of its organization, including committees and external bodies or individuals, acting on its behalf.

(2) Except as required in this part, information about a particular product, quality assurance system, Facility, or fastener manufacturer shall not be disclosed to a third party without the written consent of the fastener manufacturer.

§ 280.1111 Registrar personnel.

(a) *General provisions.* (1) The personnel of the Registrar involved in registration shall be competent for the functions they perform.

(2) Information on the relevant qualifications, training and experience of each member of the personnel involved in the registration process shall be maintained by the Registrar. Records of training and experience shall be kept up to date.

(3) Clearly documented instructions shall be available to the personnel describing their duties and responsibilities. These instructions shall be maintained up to date.

(b) *Qualification criteria for auditors and technical experts.* (1) In order to ensure that assessments are carried out effectively and uniformly, the minimum relevant criteria for competence shall be defined by the Registrar.

(2) Auditors shall meet the requirements of the appropriate international documentation. For the assessment of a quality system, the relevant guidelines for auditing and the criteria for auditors are those defined in the appropriate international documentation.

(3) Technical experts are not required to comply with the requirements for auditors, and guidance on their personal attributes may be obtained by the appropriate international documentation.

(c) *Selection procedure.* (1) The Registrar shall have a procedure for selecting auditors and, if applicable, technical experts on the basis of their competence, training, qualifications, and experience, and for initially assessing the conduct of auditors and technical experts during assessment and subsequently monitoring the performance of auditors and technical experts.

(2) When selecting the audit team to be appointed for a specific assessment, the Registrar shall ensure that the skills brought to each assignment are appropriate. The team shall:

(i) Be familiar with the Act and this part, registration procedures and registration requirements;

(ii) Have a thorough knowledge of the relevant assessment method and assessment documents;

(iii) Have appropriate technical knowledge of the fastener technology for which registration is sought and where relevant with associated procedures and their potential for failure (technical experts who are not auditors may fulfill this function);

(iv) Have a degree of understanding sufficient to make a reliable assessment of the competence of the Facility

to provide products, processes or services in its registered scope;

(v) Be able to communicate effectively, both in writing and orally, in the required languages;

(vi) Be free from any interest that might cause team members to act in other than an impartial or non-discriminatory manner, for example:

(A) Audit team members or their organization shall not have provided consulting services to the applicant or fastener manufacturer whose Facility is registered which compromise the registration process and decision; and

(B) In accordance with the directives of the Registrar, the audit team members shall inform the Registrar, prior to the assessment, about any existing, former or envisaged link between themselves or their organization and the fastener manufacturer whose Facility is to be assessed.

(d) *Contracting of assessment personnel.* The Registrar shall require the personnel involved in the assessment to sign a contract or other document by which they commit themselves to comply with the rules defined by the Registrar, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior and/or present link with the fastener manufacturers whose Facilities are to be assessed. The Registrar shall ensure that, and document how, any subcontracted assessment personnel satisfy all the requirements for assessment personnel outlined in this Subpart.

(e) *Assessment personnel records.* (1) The Registrar shall possess and maintain up-to-date records on assessment personnel, consisting of:

(i) Name and address;

(ii) Affiliation and position held in the organization;

(iii) Educational qualifications and professional status;

(iv) Experience and training in each field of competence of the Registrar;

(v) Date of most recent updating of records; and

(vi) Performance appraisal.

(2) The Registrar shall ensure and verify that any subcontracted body maintains records which satisfy the requirements of this part, of assessment personnel who are subcontracted to the Registrar.

(f) *Procedures for audit teams.* Audit teams shall be provided with up-to-date assessment instructions and all relevant information on registration arrangements and procedures.

§280.1112 Changes in the registration requirements.

The Registrar shall give due notice of any changes it intends to make in its requirements for registration. It shall take account of views expressed by the interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each fastener manufacturer whose Facility is registered carries out any necessary adjustments to its procedures within such time as, in the opinion of the Registrar, is reasonable.

§280.1113 Appeals, complaints and disputes.

Appeals, complaints and disputes brought before the Registrar by fastener manufacturers or other parties shall be subject to the procedures of the Registrar. The Registrar shall keep a record of all appeals, complaints and disputes, and remedial actions relative to registration; take appropriate corrective and preventive action; and document the actions taken and assess their effectiveness.

REQUIREMENTS FOR REGISTRATION

§280.1120 Application for registration.

(a)(1) As specified in §280.1110(g)(1) of this part, the Registrar shall maintain up-to-date a detailed description of the assessment and registration procedure, the documents containing the requirements for registration and documents describing the rights and duties of fastener manufacturers whose Facilities are registered, and shall provide them to applicants and those fastener manufacturers. The Registrar shall require that a fastener manufacturer whose Facility is registered:

(i) Always complies with the relevant provisions of this part;

(ii) Makes all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, records (including internal audit reports) and personnel for the purposes of assessment, surveillance, reassessment, and resolution of complaints;

(iii) Only claims that its Facility is registered with respect to those activities for which it has been granted registration;

(iv) Does not use the registration in such a manner as to bring the Registrar into disrepute, and does not make any statement regarding its registration which the Registrar may consider misleading or unauthorized;

(v) Upon suspension or withdrawal of the registration (however determined), discontinues use of all advertising matter that contains any reference thereto and returns any registration documents as required by the Registrar;

(vi) Uses registration only to indicate that the quality assurance system as employed in its Facility is in conformity with specified standards or other normative documents, and does not use the registration to imply that a product or service is approved by the Registrar, as required by §280.804;

(vii) Ensures that no registration document, mark or report, or any part thereof, is used in a misleading manner; and

(viii) In making reference to the registration in communication media such as documents, brochures, or advertising, complies with the requirements of the Registrar.

(2) When the desired scope of registration is related to a specific program, any necessary explanation shall be provided to the fastener manufacturer. If requested, additional application information shall be provided to the fastener manufacturer.

(b) The Registrar shall require an official application form, duly completed and signed by a duly authorized representative of the applicant fastener manufacturer in which or attached to which:

(1) The scope of the desired registration is defined; and

(2) The applicant agrees to comply with the requirements for registration and to supply any information needed for its evaluation.

(c)(1) At least the following information shall be provided by the applicant prior to the on-site assessment:

(i) The general features of the applicant, such as corporate entity, name, addresses, legal status and, where relevant, human and technical resources;

(ii) General information concerning the quality system and the activities it covers;

(iii) A description of the systems to be registered and the standards or other normative documents applicable to each; and

(iv) A copy of its quality manual and, where required, the associated documentation.

(2) The information gathered from the application documentation and the quality manual review may be used for the preparation of the on-site assessment and shall be treated with appropriate confidentiality.

§280.1121 Preparation for assessment.

(a) Before proceeding with the assessment the Registrar shall conduct, and maintain records of, a review of the request for registration to ensure that:

(1) The requirements for registration are clearly defined, documented, and understood;

(2) Any difference in understanding between the Registrar and the applicant is resolved; and

(3) The Registrar has the capability to perform the registration service with respect to the scope of the registration sought, the location of the applicant's operations, and any special requirements such as the language used by the applicant.

(b) The Registrar shall prepare a plan for its assessment activities to allow for the necessary arrangements to be made.

(c) The Registrar shall nominate a qualified audit team to evaluate all material collected from the applicant and to conduct the audit on its behalf. Experts in the areas to be assessed may be attached to the Registrar's team as advisers.

(d) The fastener manufacturer shall be informed of the names of the members of the audit team who will carry

out the assessment, with sufficient notice to appeal against the appointment of any particular auditors or experts.

(e) The audit team shall be formally appointed and provided with the appropriate working documents. The plan for and the date of the audit shall be agreed to by the fastener manufacturer. The mandate given to the audit team shall be clearly defined and made known to the fastener manufacturer, and shall require the audit team to examine the structure, policies, and procedures of the Facility and the quality assurance system it employs, and confirm that these meet all the requirements relevant to the scope of registration, and that the procedures are implemented and are such as to give confidence in the products, processes, or services of the Facility being evaluated.

§ 280.1122 Assessment.

The audit team shall asses the quality assurance system, employed in the Facility being evaluated, covered by the defined scope against all applicable registration requirements.

§ 280.1123 Assessment report.

(a) The Registrar may adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that:

(1) A meeting takes place between the audit team and the fastener manufacturer's management prior to leaving the premises, at which the audit team provides a written or oral indication regarding the conformity of the quality assurance system, as employed in particular Facility, with the particular registration requirements and provides an opportunity for the fastener manufacturer to ask questions about the findings and their basis;

(2) The audit team provides the Registrar with a report of its findings as to the conformity of the quality assurance system, as employed in the particular Facility, with all of the registration requirements;

(3) A report on the outcome of the assessment is promptly brought to the fastener manufacturer's attention by the Registrar, identifying any nonconformity to be discharged in order to comply with all of the registration requirements;

(4) The Registrar shall invite the fastener manufacturer to comment on the report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any nonconformity with the registration requirements identified during the assessment of its quality assurance system, as employed in the particular Facility, and shall inform the fastener manufacturer of the need for full or partial reassessment of its quality assurance system or whether a written declaration to be confirmed during surveillance will be considered adequate;

(5) The report shall contain as a minimum:

(i) The date(s) of the audit(s);

(ii) The name(s) of the person(s) responsible for the report;

(iii) The names and addresses of the Facility audited;

(iv) The assessed scope of registration or reference thereto, including reference to the standard(s) applied;

(v) Comments on the conformity of the quality assurance system, as employed in the particular Facility, with the registration requirements, with a clear statement of nonconformity and, where applicable, any useful comparison with the results of previous assessments of the quality assurance system, as employed in that particular Facility; and

(vi) An explanation of any differences from the information presented to the body at the closing meeting.

(b) If the final report authorized by the Registrar differs from the report referred to in paragraphs (a)(3) and (5) of this section, it shall be submitted to the fastener manufacturer with an explanation of any differences from the previous report. The report shall take into consideration:

(1) The qualification, experience, and authority of the staff encountered.

(2) The adequacy of the internal organization and procedures adopted by the applicant body to give confidence in the quality assurance system, as employed in the particular Facility; and

(3) The actions taken to correct identified nonconformities including, where applicable, those identified at previous assessments.

§ 280.1124 Decision on registration.

(a) The decision whether or not to register a fastener Facility shall be taken by the Registrar on the basis of the information gathered during the registration process and any other relevant information. Those who make the registration decision shall not have participated in the audit.

(b) The Registrar shall not delegate authority for granting, maintaining, extending, reducing, suspending, or withdrawing registration to an outside person or body.

(c) The Registrar shall provide to each fastener manufacturer whose Facility is registered, registration documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These documents shall identify, for the fastener manufacturer and the particular Facility covered by the registration:

(1) The name and addresses;

(2) The scope of registration granted, including as appropriate:

(i) The quality system standards and/or other normative documents to which quality systems are registered;

(ii) The product, process, or service categories; and, if appropriate,

(iii) Regulatory requirements, product standards, or other normative documents against which products are supplied.

(3) The effective date of registration and the term for which the registration is valid.

(d) Any application for amendment to the scope of a previously granted registration shall be processed by the Registrar. The Registrar shall decide what, if any, assessment procedure is appropriate to determine whether or not the amendment should be granted and shall act accordingly.

§ 280.1125 Surveillance and reassessment procedures.

(a) The Registrar shall carry out periodic surveillance and reassessment at sufficiently close intervals to verify that its registered Facilities continue to comply with the registration requirements. The period involved cannot be greater than one year.

(b) Surveillance and reassessment procedures shall be consistent with those concerning the assessment of the Facility as described in this part.

§ 280.1126 Use of certificates and logos.

(a) The Registrar shall exercise proper control over ownership, use and display of its quality system registration mark and logos.

(b) If the registrar confers the right to use a symbol or logo to indicate registration of a Facility, the fastener manufacturer may use the specified symbol or logo only as authorized in writing by the Registrar. This symbol or logo shall not be used on a product or in a way that may be interpreted as denoting product conformity.

(c) The Registrar shall take suitable action to deal with incorrect references to the registration system or misleading use of certificates and logos found in advertisements, catalogs, etc. Such action could include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.

§ 280.1127 Access to records of complaints to fastener manufacturers.

The Registrar shall require each fastener manufacturer whose Facility is registered to make available to the Registrar, when requested, the records of all complaints and corrective action taken in accordance with the requirements of the quality system standards or other normative documents.

PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

Subpart A—General Information

Sec.

Subpart B—Establishing a LAP

Subpart C—Accrediting a Laboratory

Subpart D—Conditions and Criteria For Accreditation

AUTHORITY: 15 U.S.C. 272 *et seq.*

SOURCE: 49 FR 44623, Nov. 8, 1984, unless otherwise noted. Redesignated at 59 FR 22745, May 3, 1994.

Subpart A—General Information

§ 285.1 Purpose.

The purpose of part 285 is to set out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates to accredit both calibration laboratories and testing laboratories in response to:

(a) Mandates by the Federal government through legislative or administrative action;

(b) Requests from a government agency (§ 285.13); and

(c) Requests from a private sector organization (§ 285.14).

Supplementary technical and administrative requirements are provided in supporting handbooks and documents as needed depending on the criteria established for specific Laboratory Accreditation Programs (LAPs).

§ 285.2 Organization of procedures.

Subpart A describes considerations which relate in general to all aspects of NVLAP. Subpart B describes how new LAPs are requested, developed, and announced, and how LAPs are terminated. Subpart C describes procedures for accrediting laboratories. Subpart D sets out the conditions and criteria for NVLAP accreditation.

§ 285.3 Description and goal of NVLAP.

(a) NVLAP is a system for accrediting calibration laboratories and testing laboratories found competent to perform specific tests or calibrations. Competence is defined as the ability of a laboratory to meet the NVLAP conditions (§ 285.32) and to conform to the criteria (§ 285.33) in NVLAP publications for specific calibration and test methods.

(b) NVLAP is a process which:

(1) Provides the technical and administrative mechanisms for national and international recognition for competent laboratories based on a comprehensive procedure for promoting confidence in calibration and testing laboratories that show that they operate in accordance with NVLAPs requirements;

(2) Provides laboratory management with documentation for use in the development and implementation of their quality systems;

(3) Identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems;

(4) Provides laboratories with guidance from technical experts to aid them in reaching a higher level of performance resulting in the generation of improved engineering and product information; and

(5) Promotes the acceptance of calibration and test results between countries, and facilitates cooperation between laboratories and other bodies to assist in the exchange of information and experience, facilitating removal of non-tariff barriers to trade and promoting the harmonization of standards and procedures.

(c) NVLAP is comprised of a series of laboratory accreditation programs (LAPs) which are established on the basis of requests and demonstrated need. The specific calibration and test methods, types of calibration and test methods, products, services, or standards to be included in a LAP are determined by an open process during the

establishment of the LAP (see § 285.11). The Director of the National Institute of Standards and Technology (NIST) does not unilaterally propose or decide the scope of a LAP. Communication with other laboratory accreditation systems is fostered to encourage development of common criteria and approaches to accreditation and to promote the domestic, foreign, and international acceptance of test data produced by the accredited laboratories.

§ 285.4 References.

NVLAP is designed to be compatible with domestic and foreign laboratory accreditation programs to ensure the universal acceptance of test data produced by NVLAP-accredited laboratories. In this regard, these Procedures are compatible with:

(a) The most recent official publications of ISO Guides 2, 25, 30, 38, 43, 45, 49, 58, and Standards 8402, 9001, 9002, 9003, and 9004.

(b) International vocabulary of basic and general terms in metrology (VIM) and Guide to the expression of uncertainty in measurement, issued by International Bureau of Weights and Measures (BIPM), International Electrotechnical Commission (IEC), International Federation of Clinical Chemistry (IFCC), International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), International Union of Pure and Applied Physics (IUPAP), and International Organization of Legal Metrology (OIML).

§ 285.5 Definitions.

Accreditation (of a laboratory): A formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of test or calibrations.

Accreditation criteria: A set of requirements used by an accrediting body which a laboratory must meet in order to be accredited.

Approved Signatory (of an accredited laboratory): An individual who is recognized by NVLAP as competent to sign accredited laboratory calibration or test reports.

Assessment (of a laboratory): The onsite examination of a testing or calibration laboratory to evaluate its compliance with the conditions and criteria for accreditation.

Authorized Representative (of an accredited laboratory): An individual who is authorized by the laboratory or the parent organization to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements (The Authorized Representative may also be recommended by the laboratory as an Approved Signatory).

Calibration: A set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system, or values represented by a material measure, and the corresponding known values of a measurand.

Calibration method: A defined technical procedure for performing a calibration.

Certificate of Accreditation: A document issued by NVLAP to a laboratory that has met the criteria and conditions for accreditation. The Certificate of Accreditation may be used as proof of accredited status. A Certificate of Accreditation is always accompanied with a Scope of Accreditation.

Competence: The ability of a laboratory to meet the NVLAP conditions and to conform to the criteria in NVLAP publications for specific calibration and test methods.

Deficiency: The non-fulfillment of NVLAP conditions and/or criteria for accreditation.

Director of NIST: The Director of the National Institute of Standards and Technology or designate.

Laboratory: An organization that performs calibrations and/or tests. When a laboratory is part of an organization that carries out activities additional to calibration and testing, the term ''laboratory'' refers only to those parts of that organization that are involved in the calibration and testing process. The laboratory activities may be carried out at or from a permanent location, at or from a temporary facility, or in or from a mobile facility.

LAP: A laboratory accreditation program established and administered under NVLAP, consisting of test methods or calibrations relating to specific products or fields of testing or calibration.

NIST: The National Institute of Standards and Technology.

NVLAP: The National Voluntary Laboratory Accreditation Program. NVLAP is an Office within the National Institute of Standards and Technology.

Person: Associations, companies, corporations, educational institutions, firms, government agencies at the federal, state and local level, partnerships, and societies—as well as divisions thereof—and individuals.

Product: A type or a category of manufactured goods, constructions, installations, and natural and processed materials, or those associated services whose characterization, classification, or functional performance is specified by standards or test methods.

Proficiency testing: The determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Quality manual: A document stating the quality policy, quality system, and quality practices of an organization. The quality manual may reference other laboratory documentation.

Quality system: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. A ''certified reference material'' means that one or more of the property values of the reference material are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

Reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

Scope of accreditation: A document issued by NVLAP which lists the test methods or services, or calibration services for which the laboratory is accredited.

Sub-facility: A laboratory operating under the technical direction and quality system of a main facility that is accredited.

Test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

Test method: A defined technical procedure for performing a test.

Testing laboratory: A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products or materials.

Traceability of the accuracy of measuring instruments: A documented chain of comparison connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and ultimately to a primary standard.

§ 285.6 NVLAP documentation.

NVLAP publications are available for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for accreditation under the NVLAP program. Accredited laboratories will be sent revised publications routinely. Publications include:

(a) The Procedures and General Requirements, (15 CFR part 285);

(b) Handbooks containing the administrative and operational procedures and technical requirements of specific LAPs;

(c) A directory of accredited laboratories published annually and updated periodically; and

(d) Policy Guides that provide changes to the Procedures and General Requirements and Handbooks between formal revisions of those publications.

§ 285.7 Confidentiality.

To the extent permitted by applicable laws, NVLAP will seek to ensure confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing,

evaluation, and accreditation of laboratories.

§ 285.8 Referencing NVLAP accreditation.

To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(a) Follow NVLAP guidance when advertising its accredited status (including the use of the NVLAP logo) on letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications.

(b) Inform its clients that the laboratory's accreditation or any of its calibration or test reports in no way constitutes or implies product certification, approval, or endorsement by NIST.

[59 FR 22747, May 3, 1994]

Subpart B—Establishing a LAP

§ 285.11 Requesting a LAP.

(a) A request to establish a LAP must be made to the Director of NIST.

(b) Each request must be in writing and must include:

(1) The scope of the LAP in terms of products, calibration services, or testing services proposed for inclusion;

(2) Specific identification of the applicable standards and test methods including appropiate designations, and the orgainizations or standards writing bodies having responsibility for them;

(3) A statement of need for the LAP including:

(i) Evidence of a national need to accredit calibration or testing laboratories for the specific scope beyond that served by an existing laboratory accreditation program in the public or private sector;

(ii) Evidence of a national need to accredit testing laboratories for the specific scope beyond that served by an existing laboriatory accreditation program in the public or private sector;

(iii) An estimate of the number of laboratories that may seek accreditation; and

(iv) An estimate of the number and nature of the users of such laboratories; and

(4) A stratement of the extent to which the requestor is willing to support necessary developmental aspects of the LAP with funding and personnel.

(c) NVLAP may request clarification of the information submitted according to paragraph (b) of this section.

(d) Before determining the need for a LAP, the Director of NIST shall publish a FEDERAL REGISTER notice of the receipt of a LAP request if the request complies with §7.11(b). The notice will:

(1) Describe the scope of the requested LAP;

(2) Indicate how to obtain a copy of the request; and

(3) State that anyone may submit comments on the need for a LAP to NVLAP within 60 days of the date of the notice.

(e) Following receipt of the identification of a mandate for a LAP based on legislative or administrative action, the Director shall publish a FEDERAL REGISTER notice:

(1) Stating the purpose of the LAP including the national or international need;

(2) Describing the general scope of the LAP;

(3) Identifying government agencies having oversight; and

(4) Providing information to any interested party wishing to be on the NVLAP mailing list to receive routine information on the development of the LAP.

(f) Consistent with applicable laws and regulations, the Director may negotiate and conclude agreements with the governments of other countries for NVLAP recognition of foreign laboratories. At a minimum, any agreement must provide that accredited foreign laboratories meet conditions for accreditation comparable to and consistent with those set out in these requirements.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38314, Sept. 18, 1990. Redesignated and amended at 59 FR 22747, May 3, 1994]

§ 285.12 LAP development decision.

(a) The Director of NIST shall establish all LAPs on the basis of need.

(1) A mandate to develop a LAP by NVLAP will be interpreted as a de facto decision to develop the specified LAP, and a LAP will be developed (or existing LAPs modified, if practical) following these procedures.

(2) Government agencies may document the need by using §285.13, and private sector organizations by using §285.14.

(b) After receipt of the request, the Director of NIST shall analyze it to determine if a need exists for the requested LAP. In making this determination, the Director of NIST shall consider the following:

(1) The needs and scope of the LAP initially requested;

(2) The needs and scope of the user population;

(3) The nature and content of other relevant public and private sector laboratory accreditation programs;

(4) Compatibility with the criteria referenced in §7.33;

(5) The importance of the requested LAP to commerce, consumer well-being, or the public health and safety;

(6) The economic and technical feasibility of accrediting laboratories for the calibration or test methods, types of calibration or test methods, products, services, or standards requested; and

(7) Recommendations from written comments for altering the scope of the requested LAP by adding or deleting test methods, types of test methods, products, services, or standards.

(c) If the Director of NIST decides that a need has been demonstrated, and if resources are available to develop a LAP, NVLAP shall notify interested persons of the decision to proceed with development of a LAP.

(d) If the Director of NIST concludes that there is a need for a LAP but there are no resources for development, NVLAP shall notify the requestor and other interested persons of the decision not to proceed until resources become available.

(e) If the Director of NIST decides that a need for a LAP has not been demonstrated, NVLAP shall notify the requestor and other interested persons of the decision and the reasons not to proceed with development of a LAP.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38314, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994]

§285.13 Request from a government agency.

(a) Any Federal, state or local agency responsible for regulatory or public service programs established under statute or code, which has determined a need to accredit laboratories within the context of its programs, may request the Director of NIST to establish a LAP.

(b) Each request must be in writing and must include the information required in §7.11(b) and:

(1) A description of the procedures followed or a citation of the specific authority used to determine the need for a LAP; and

(2) For state and local government agencies, a statement of why the LAP should be of national scope.

(c) NVLAP may request clarification of the information required by §285.11(b).

(d) Before deciding to proceed with the development of a LAP, the Director of NIST shall publish a FEDERAL REGISTER notice of the receipt of a LAP request. The notice will indicate how to obtain a copy of the request and will state that anyone may submit comments on the need for a LAP to the requesting government agency within 60 days of the date of the notice.

(e) NVLAP shall notify interested persons of the decision to proceed or not to proceed with development of a LAP.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38314, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994]

§285.14 Request from a private sector organization.

(a) Any private sector organization which has determined a need to accredit laboratories for specific products, calibrations, or testing services, may request the Director of NIST to establish a LAP if it uses procedures meeting the following conditions:

(1) Public notice of meetings and other activities including requests for LAPs is provided in a timely fashion and is distributed to reach the attention of interested persons;

(2) Meetings are open and participation in activities is available to interested persons;

(3) Decisions reached by the private sector organization in the development of a request for a LAP represent substantial agreement of the interested persons;

(4) Prompt consideration is given to the expressed views and concerns of interested persons;

(5) Adequate and impartial mechanisms for handling substantive and procedural complaints and appeals are in place; and

(6) Appropriate records of all meetings are maintained and the official procedures used by the private sector organization to make a formal request for a LAP are made available upon request to any interested person.

(b) Each request must be in writing and must include the information required in §7.11(b) and a description of the way in which the organization has met the conditions specified in paragraph (a) of this section.

(c) NVLAP may request clarification of the information required by §285.11(b).

(d) Before deciding to proceed with development of a LAP, the Director of NIST shall publish a FEDERAL REGISTER notice of the receipt of a LAP request. The notice will indicate how to obtain a copy of the request and will state that anyone may submit comments on the need for a LAP to the requesting private sector organization within 60 days of the date of the notice.

(e) NVLAP shall notify interested persons of the decision to proceed or not to proceed with development of a LAP.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38314, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994]

§285.15 Development of technical requirements.

(a) Technical requirements for accreditation are specific for each LAP. The requirements tailor the criteria referenced in §285.33 to the calibration or test methods, types of calibration or test methods, products, services, or standards covered by the LAP.

(b) NVLAP shall develop the technical requirements based on expert advice. This advice may be obtained through one or more informal public workshops or other suitable means.

(c) NVLAP shall make every reasonable effort to ensure that the affected calibration or testing community within the scope of the LAP is informed of any planned workshop. Summary minutes of each workshop will be prepared. A copy of the minutes will be made available for inspection and copying at the NIST Records Inspection Facility.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994]

§285.16 Coordination with Federal agencies.

As a means of assuring effective and meaningful cooperation, input, and participation by those federal agencies that may have an interest in and may be affected by established LAPs, NVLAP shall communicate and consult with appropriate officials within those agencies.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated at 59 FR 22745, May 3, 1994]

§285.17 Announcing the establishment of a LAP.

(a) When NVLAP has completed the development of the technical requirements of the LAP and established a schedule of fees for accreditation, NVLAP shall publish a notice in the FEDERAL REGISTER announcing the establishment of the LAP.

(b) The notice will:

(1) Identify the scope of the LAP; and

(2) Advise how to apply for accreditation.

(c) NVLAP shall establish fees in amounts that will enable it to recover its full costs, and shall, from time to time as necessary, revise the fees for this purpose.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 22748, May 3, 1994]

§285.18 Adding to or modifying an established LAP.

(a) Established or developing LAPs may be added to, modified, or realigned based on either a written request from any person wishing to add or delete specific standards, calibration or test methods, or types of calibration or test methods or a need identified by NIST.

(b) NVLAP may choose to make the additions or modifications available for accreditation under a LAP when:

(1) The additional standards, calibration or test methods, or types of calibration or test methods requested are directly relevant to the LAP;

(2) It is feasible and practical to accredit calibration or testing laboratories for the additional standards, calibration or test methods, or types of calibration or test methods; and

(3) It is likely that laboratories will seek accreditation for the additional standards, calibration or test methods, or types of calibration or test methods.

[59 FR 22748, May 3, 1994]

§ 285.19 Termination of a LAP.

(a) The Director of NIST may terminate a LAP when the Director of NIST determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP. In the event that the Director of NIST proposes to terminate a LAP, a notice will be published in the FEDERAL REGISTER setting forth the basis for that determination.

(b) The notice published under paragraph (a) of this section will provide a 60-day period for submitting written comments on the proposal to terminate the LAP. All written comments will be made available for public inspection and copying at the NIST Records Inspection Facility.

(c) After the comment period, the Director of NIST shall determine if public support exists for the continuation of the LAP. If public comments support the continuation of the LAP, the Director of NIST shall publish a FEDERAL REGISTER notice announcing the continuation of the LAP. If public support does not exist for continuation, the LAP will be terminated effective 90 days after the date of the published notice of intent to terminate the LAP.

(d) If the LAP is terminated, NVLAP shall no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted will remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994]

Subpart C—Accrediting a Laboratory

§ 285.21 Applying for accreditation.

(a) A laboratory may complete and remit an application for accreditation in any of the established LAPs.

(b) Upon receipt of a laboratory's application, NVLAP shall:

(1) Acknowledge receipt of the application;

(2) Request further information, if necessary;

(3) Confirm payment of fees before proceeding with the accreditation process; and

(4) Specify the next step(s) in the accreditation process.

(c) Accreditation of laboratories outside of the United States may require:

(1) Translation of laboratory documentation into English; and

(2) Payment of additional traveling expenses for on-site assessments and proficiency testing.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 27748, May 3, 1994]

§ 285.22 Assessing and evaluating a laboratory.

(a) Information use to evaluate a laboratory's compliance with the conditions for accreditation set out in § 285.32, the criteria for accreditation set out in § 285.33, and the technical requirements established for each LAP will include (not necessarily in this order):

(1) Application and other material submitted by the laboratory (§ 285.32(b));

(2) On-site assessment reports;

(3) Laboratory performance on proficiency tests;

(4) Laboratory responses to identified deficiencies; and

(5) Technical evaluation.

(b) NVLAP shall arrange the assessment and evaluation of applicant laboratories in such a way as to minimize potential conflicts of interest.

(c) NVLAP shall inform each applicant laboratory of any additional action(s) that the laboratory must take to qualify for accreditation.

[59 FR 22748, May 3, 1994]

§ 285.23 Granting and renewing accreditation.

(a) NVLAP will take action to: (1) Grant initial accreditation, or (2) renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies with the specific NVLAP requirements.

(b) If accreditation is granted or renewed, NVLAP shall:

(1) Provide a Certificate of Accreditation and a Scope of Accreditation to the laboratory;

(2) Provide guidance on referencing the laboratory's accredited status, and the use of the NVLAP logo by the laboratory and its clients, as needed; and

(3) Remind the laboratory that accreditation does not relieve it from complying with applicable federal, state, and local laws and regulations.

(c) NVLAP shall notify an accredited laboratory at least 30 days before its accreditation expires advising of the action(s) the laboratory must take to renew its accreditation.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated and amended at 59 FR 27749, May 3, 1994]

§ 285.24 Denying, suspending, and revoking accreditation.

(a) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

(b) The laboratory will have 30 days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within that 30-day period.

(c) If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may, after consultation with the laboratory, suspend the laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation. If accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated.

(d) A laboratory whose accreditation has been denied, revoked, terminated, or expired, or which has withdrawn its application before being accredited, may reapply and be accredited if the laboratory:

(1) Completes the assessment and evaluation process; and

(2) Meets the conditions and criteria for accreditation that are set out in §§ 285.32 and 285.33.

(e) Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports during the suspension period. The determination of NVLAP whether to suspend or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

[59 FR 22749, May 3, 1994]

§ 285.25 Voluntary termination of accreditation.

A laboratory may at any time terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so. NVLAP shall terminate the laboratory's accreditation and shall notify the laboratory stating that its accreditation has been terminated in response to its request.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38315, Sept. 18, 1990. Redesignated at 59 FR 22745, May 3, 1994]

§ 285.26 Change in status of laboratory.

Accreditation of a laboratory is based on specific conditions and criteria including the laboratory ownership, location, staffing, facilities, and configuration. Changes in any of these

conditions or criteria could result in loss of accreditation. NVLAP must be informed if any of the conditions or criteria for accreditation are changed so that a determination can be made concerning the status of the accreditation.

[59 FR 22749, May 3, 1994]

Subpart D—Conditions and Criteria For Accreditation

§285.31 Application of accreditation conditions and criteria.

To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in §285.32, the criteria set out in §285.33, and the guidance provided in the Handbooks for specific LAPs.

[59 FR 22749, May 3, 1994]

§285.32 Conditions for accreditation

(a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(1) Be assessed and evaluated initially and on a periodic basis;

(2) Demonstrate, on request, that it is able to perform the calibrations or tests representative of those for which it is seeking accreditation;

(3) Pay all fees;

(4) Participate in proficiency testing as required;

(5) Be capable of performing the calibrations or tests for which it is accredited according to the latest version of the calibration or test method within one year after its publication or within another time limit specified by NVLAP;

(6) Limit the representation of the scope of its accreditation to only those calibrations, tests or services for which accreditation is granted;

(7) Resolve all deficiencies;

(8) Limit all its work or services of clients to those areas where competence and capacity are available;

(9) Maintain records of all actions taken in response to complaints for a minimum of one year;

(10) Maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render calibration or test reports objectively and without bias is not adversely affected;

(11) Report to NVLAP within 30 days any major changes involving the location, ownership, management structure, authorized representative, approved signatories, or facilities of the laboratory; and

(12) Return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for revision or other action should it:

(i) Be requested to do so by NVLAP;

(ii) Voluntarily terminate its accredited status; or

(iii) Become unable to conform to any of these conditions, the applicable criteria of §285.33, and related technical requirements.

(b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information:

(1) Legal name and full address;

(2) Ownership of the laboratory;

(3) Organization chart defining relationships that are relevant to performing testing and calibrations covered in the accreditation request;

(4) General description of the laboratory, including its facilities and scope of operation;

(5) Name, address, and telephone and FAX number of the authorized representative of the laboratory;

(6) Names or titles and qualifications of laboratory staff nominated to serve as approved signatories of calibration or test reports that reference NVLAP accreditation;

(7) The laboratory Quality Manual; and

(8) Other information as may be needed for the specific LAP(s) in which accreditation is sought.

[59 FR 22749, May 3, 1994]

§285.33 Criteria for accreditation.

(a) *Scope.* (1) This section sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

(2) Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by NVLAP, depending

upon the specific character of the task of the laboratory.

(3) This section is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

(b) *Organization and management.* (1) The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet these requirements.

(2) The laboratory shall:

(i) Have managerial staff with the authority and resources needed to discharge their duties;

(ii) Have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

(iii) Be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

(iv) Specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

(v) Provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

(vi) Have a technical manager (however named) who has overall responsibility for the technical operations;

(vii) Have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

(viii) Nominate deputies in case of absence of the technical or quality manager;

(ix) Have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

(x) Where appropriate, participate in interlaboratory comparisons and proficiency testing programs.

(c) *Quality system, audit and review.* (1) The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

(2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of procedures. The quality manual and related quality documentation shall also contain:2

(i) A quality policy statement, including objectives and commitments, by top management;

(ii) The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

(iii) The relations between management, technical operations, support services and the quality system;

(iv) Procedures for control and maintenance of documentation;

(v) Job descriptions of key staff and reference to the job descriptions of other staff;

(vi) Identification of the laboratory's approved signatories;

(vii) The laboratory's procedures for achieving traceability of measurements;

(viii) The laboratory's scope of calibrations and/or tests;

(ix) Arrangements for ensuring that the laboratory reviews all new work to

ensure that it has the appropriate facilities and resources before commencing such work;

(x) Reference to the calibration, verification and/or test procedures used;

(xi) Procedures for handling calibration and test items;

(xii) Reference to the major equipment and reference measurement standards used;

(xiii) Reference to procedures for calibration, verification and maintenance of equipment;

(xiv) Reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

(xv) Procedures to be followed for feedback and corrective action whenever discrepancies are detected, or departures from documented policies and procedures occur;

(xvi) The laboratory management policies for departures from documented policies and procedures or from standard specifications;

(xvii) Procedures for dealing with complaints;

(xviii) Procedures for protecting confidentiality and proprietary rights;

(xix) Procedures for audit and review.

(3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

(4) The quality system adopted to satisfy the requirements of this section shall be reviewed at least once each year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

(5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate but not be limited to:

(i) Internal quality control schemes using whenever possible statistical techniques;

(ii) Participation in proficiency testing or other interlaboratory comparisons;

(iii) Regular use of certified reference materials and/or in—house quality control using secondary reference materials;

(iv) Replicate testings using the same or different methods;

(v) Re-testing of retained items;

(vi) Correlation of results for different characteristics of an item.

(d) *Personnel.* (1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

(3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) *Accommodation and environment.* (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

(2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

(3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

(4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

(5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

(6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

(f) *Equipment and reference materials.* (1) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this section are met.

(2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

(3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

(4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

(i) The name of the item of equipment;

(ii) The manufacturer's name, type identification, and serial number or other unique identification;

(iii) Date received and date placed in service;

(iv) Current location, where appropriate;

(v) Condition when received (e.g. new, used, reconditioned);

(vi) Copy of the manufacturer's instructions, where available;

(vii) Dates and results of calibrations and/or verifications and date of next calibration and/or verification;

(viii) Details of maintenance carried out to date and planned for the future;

(ix) History of any damage, malfunction, modification or repair.

(g) *Measurement traceability and calibration.* (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment.

(2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

(3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

(4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

(5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

(6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

(7) Reference materials shall, where possible, be traceable to national or

international standards of measurement, or to national or international standard reference materials.

(h) *Calibration and test methods.* (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

(3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

(4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

(5) Where sampling is carried out as part of the test method, the laboratory shall used documented procedures and appropriate statistical techniques to select samples.

(6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

(i) The requirements of these procedures are complied with;

(ii) Computer software is documented and adequate for use;

(iii) Procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

(iv) Computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

(v) It establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

(8) Documented procedure shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

(i) *Handling of calibration and test items.* (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

(2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Were there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

(3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a

calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

(4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

(j) *Records.* (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

(2) All records (including those listed in § 285.33(f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

(k) *Certificates and reports.* (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

(2) Each certificate or report shall include at least the following information:

(i) A title, e.g., ''Calibration Certificate'', ''Test Report'' or ''Test Certificate'';

(ii) Name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

(iii) Unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

(iv) Name and address of client, where appropriate;

(v) Description and unambiguous identification of the item calibrated or tested;

(vi) Characterization and condition of the calibration or test item;

(vii) Date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

(viii) Identification of the calibration or test method used, or unambiguous description of any non-standard method used;

(ix) Reference to sampling procedure, where relevant;

(x) Any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions;

(xi) Measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

(xii) A statement of the estimated uncertainty of the calibration or test result (where relevant);

(xiii) A signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

(xiv) Where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

(xv) A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

(3) Where the certificate or report contains results of calibrations or tests performed by sub-contractors, these results shall be clearly identified.

(4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried

out, but the headings shall be standardized as far as possible.

(5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement ''Supplement to Calibration Certificate for Test Report or Test Certificate), serial number * * * for as otherwise identified]'', or equivalent form of wording. Such amendments shall meet all the relevant requirements of §285.33(j).

(6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate of amendment to a report or certificate.

(7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of these procedures are met and that confidentiality is preserved.

(l) *Subcontracting of calibration or testing.* (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the calibration or testing to another party.

(2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

(m) *Outside support services and supplies.* (1) Where the laboratory procures outside services and supplies, other than those referred to in these procedures, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

(2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) *Complaints.* (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

(2) Where a complaint, or any other circumstances, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with this section.

[59 FR 22750, May 3, 1994]

PART 286—NATIONAL VOLUNTARY CONFORMITY ASSESSMENT SYSTEM EVALUATION (NVCASE) PROGRAM

Sec.

AUTHORITY: 15 U.S.C. 272 *et seq.*

SOURCE: 59 FR 19131, Apr. 22, 1994, unless otherwise noted.

§ 286.1 Purpose.

The purpose of this program is to enable U.S. industry to satisfy mandated foreign technical requirements using the results of U.S.-based conformity assessment programs that perform technical evaluations comparable in their rigor to practices in the receiving country. Under this program, the Department of Commerce, acting through the National Institute of Standards and Technology, evaluates U.S.-based conformity assessment bodies in order to be able to give assurances to a foreign government that qualifying bodies meet that government's requirements and can provide results that are acceptable to that government. The program is intended to provide a technically-based U.S. approval process for U.S. industry to gain foreign market access; the acceptability of conformity assessment results to the relevant foreign government will be a matter for agreement between the two governments.

§ 286.2 Scope.

(a) For purposes of this program, conformity assessment consists of product sample testing, product certification, and quality system registration. Associated activities can be classified by level:

(1) *Conformity level:* This level encompasses comparing a product, process, service, or system with a standard or specification. As appropriate, the evaluating body can be a testing laboratory, product certifier or certification body, or quality system registrar.

(2) *Accreditation level:* This level encompasses the evaluation of a testing laboratory, a certification body, or a quality system registrar by an independent body—an accreditation body—based on requirements for the acceptance of these bodies, and the granting of accreditation to those which meet the established requirements.

(3) *Recognition level:* This level encompasses the evaluation of an accreditation body based on requirements for its acceptance, and the recognition by the evaluating body of the accreditation body which satisfies the established requirements.

(b) NIST operates the NVCASE program as follows:

(1) *Conformity level:* Under this program NIST accepts requests for evaluations of U.S. bodies involved in activities related to conformity assessment. NIST does not perform conformity assessments as part of the program and therefore does not accept requests for such evaluations.

(2) *Accreditation level:* NIST accepts requests for accreditation of conformity assessment bodies only when (i) directed by U.S. law; (ii) requested by another U.S. government agency; or (iii) requested to respond to a specific U.S. industrial or technical need, relative to a mandatory foreign technical requirement, if it has been determined after public consultation that (A) there is no satisfactory accreditation alternative available and the private sector has declined to make acceptable accreditation available, and (B) there is evidence that significant public disadvantage would result from the absence of any alternative.

(3) *Recognition level:* NIST accepts requests for recognition of bodies that accredit testing laboratories, certification bodies, and quality system registrars when (i) directed by U.S. law; (ii) requested by another U.S. government agency; or (iii) requested to respond to a specific U.S. industrial or technical need relative to a mandatory foreign technical requirement if it has been determined after public consultation that (A) there is no suitable alternative available and (B) there is evidence that significant public disadvantage would result from the absence of any alternative.

§ 286.3 Objective.

The objective of the program is to identify the activities of requesting U.S.-based conformity assessment bodies that have been evaluated as meeting requirements established for their acceptance by foreign governments. The evaluations may be provided by NIST or by bodies recognized by NIST for this purpose under the scope of this program.

§ 286.4 Implementation.

The program is operated on a cost reimbursable basis. It is open for voluntary participation by any U.S.-based body that conducts activities related to conformity assessment falling within the program's scope. A common procedural approach is followed in responding to a request to participate. (See § 286.7 Evaluation process.) All evaluation activities rely on the use of generic program requirements based on standards and guides for the operation and acceptance of activities related to conformity assessment. Specific criteria for use in each evaluation are derived from the program requirements, as appropriate, for the mandated foreign technical requirements specified in the request to participate. A request involving a foreign technical requirement not previously addressed by NVCASE will result in an announcement of NIST's intent to develop evaluation criteria specific to the relevant requirements. NIST will contact all cognizant and interested federal agencies to coordinate appropriate actions and procedures.

§ 286.5 Program requirements.

NIST provides and maintains documented generic requirements to be applied in evaluations related to accreditation and recognition within the scope of the program. Available documentation is provided on request to prospective program participants and other interested parties. Generic requirements are developed with public input and are based on guides for the acceptance of conformity assessment activities issued by such international organizations as the International Organization for Standardization and the International Electrotechnical Commission. NIST also provides and maintains documented criteria provided in response to requests for evaluations specific to mandated foreign technical requirements. Criteria are developed with public input derived from the application and interpretation of generic program requirements in relation to specified mandated requirements. Both documented generic requirements and specific criteria are developed and maintained with input from the public.

§ 286.6 Public consultation.

NIST relies on substantial advice and technical assistance from all parties interested in program requirements and related specific criteria. Interested U.S. government agencies are routinely to be informed of prospective NVCASE actions, and advice is sought from those agencies on any actions of mutual interest. In preparing program documentation, input is also sought from workshops announced in the FEDERAL REGISTER and open tothe general public and other public means to identify appropriate standards and guides and to develop and maintain generic requirements, based on the identified standards and guides. Where relevant Federal advisory committees are available, their advice may also be sought. Similar procedures will be followed with respect to each request for evaluation which necessitates the development of criteria, derived from the generic requirements, specific to mandated foreign technical requirements.

§ 286.7 Evaluation process.

(a) Each applicant requesting to be evaluated under NVCASE is expected to initiate the process and assume designated responsibilities as NIST proceeds with its evaluation:

(1) *Application.* The applicant completes and submit a request to be evaluated.

(2) *Fee.* The applicant submits a partial payment with the application and agrees to submit the remaining balance based on evaluation costs as a condition for satisfactory completion of the process.

(3) *Documentation.* The applicant operates a system and procedures that meet the applicable generic requirements and specific criteria. Relevant documentation submitted with the application is reviewed by NIST.

(4) *On-site assessment.* The applicant and NIST cooperate in the scheduling and conduct of all necessary on-site evaluations, including the resolution of any deficiencies cited.

(5) *Final review.* The applicant provides any supplementary materials requested by NIST, then NIST completes the review and decides on appropriate action.

(b) NIST may take one of the following actions with regard to an applicant:

(1) *Certificate.* If an applicant fully demonstrates conformity with all program requirements and specific criteria, NIST issues a certificate documenting this finding. Each certificate is accompanied by a document describing the specific scope of the accreditation or recognition.

(2) *Denial.* If an applicant cannot demonstrate conformity with all program requirements and specific criteria, NIST may deny award of the certificate. An applicant who has failed to complete the evaluation satisfactorily may reapply when prepared to demonstrate full conformance with program requirements.

§ 286.8 Confidentiality of information.

All information collected relative to an applicant during an evaluation is maintained as confidential. Information is released only as required under the terms of the Freedom of Information Act or other legal requirement, subject to the rules of the Department of Commerce for such disclosure as found in 15 CFR part 4.

§ 286.9 Maintaining recognized status.

Each program participant remaining in the program shall continuously meet all program requirements and cooperate with NIST in the conduct of all surveillance and reassessment activities. Participants shall reimburse NIST for expenses incurred for these purposes.

§ 286.10 Appeal.

Any applicant or other affected party may appeal to the NIST Director any action taken under the program. When appropriate, the Director may seek an independent review by the Deputy Chief Counsel.

§ 286.11 Listings.

(a) NIST maintains lists of all bodies holding current NIST program certificates, together with the assessment areas for which they are issued.

(b) NIST also maintains lists of those qualified conformity assessment bodies that are currently accredited by bodies recognized by NIST, along with the activities of the assessment bodies within the scope of the NIST recognition program.

(c) The lists are made available to the public through various media, e.g., printed directories, electronic bulletin boards, or other means to ensure accessibility by all potential users.

(d) With respect to the lists specified in paragraph (a) and (b) of this section, NIST may delist any body if it determines the action to be in the public interest.

§ 286.12 Terminations.

(a) *Voluntary termination.* Any participant may voluntarily terminate participation at any time by written notification to NIST.

(b) *Involuntary termination.* If a participant does not continue to meet all program requirements, or if NIST determines it to be necessary in the public interest, NIST may withdraw that participant's certificate. A body that has had its status as a certificate holder terminated may reapply when prepared to demonstrate full conformance with program requirements.

SUBCHAPTER K—ADVANCED TECHNOLOGY PROGRAM PROCEDURES

PART 290—REGIONAL CENTERS FOR THE TRANSFER OF MANUFACTURING TECHNOLOGY

AUTHORITY: 15 U.S.C. 278k.

SOURCE: 55 FR 38275, Sept. 17, 1990, unless otherwise noted.

§290.1 Purpose.

This rule provides policy for a program to establish Regional Centers for the Transfer of Manufacturing Technology as well as the prescribed policies and procedures to insure the fair, equitable and uniform treatment of proposals for assistance. In addition, the rule provides general guidelines for the management of the program by the National Institute of Standards and Technology, as well as criteria for the evaluation of the Centers, throughout the lifecycle of financial assistance to the Centers by the National Institute of Standards and Technology.

§290.2 Definitions.

(a) The phrase *advanced manufacturing technology* refers to new technologies which have recently been developed, or are currently under development, for use in product or part design, fabrication, assembly, quality control, or improving production efficiency.

(b) The term *Center* or *Regional Center* means a NIST-established Regional Center for the Transfer of Manufacturing Technology described under these procedures.

(c) The term *operating award* means a cooperative agreement which provides funding and technical assistance to a Center for purposes set forth in §290.3 of these procedures.

(d) The term *Director* means the Director of the National Institute of Standards and Technology.

(e) The term *NIST* means the National Institute of Standards and Technology, U.S. Department of Commerce.

(f) The term *Program* or *Centers Program* means the NIST program for establishment of, support for, and cooperative interaction with Regional Centers for the Transfer of Manufacturing Technology.

(g) The term *qualified proposal* means a proposal submitted by a nonprofit organization which meets the basic requirements set forth in §290.5 of these procedures.

(h) The term *Secretary* means the Secretary of Commerce.

(i) The term *target firm* means those firms best able to absorb advanced manufacturing technologies and techniques, especially those developed at NIST, and which are already well prepared in an operational, management and financial sensse to improve the levels of technology they employ.

§290.3 Program description.

(a) The Secretary, acting through the Director, shall provide technical and financial assistance for the creation and support of Regional Centers for the Transfer of Manufacturing Technology. Each Center shall be affiliated with a U.S.-based nonprofit institution or organization which has submitted a qualified proposal for a Center Operating Award under these procedures. Support may be provided for a period not to exceed six years. The Centers work with industry, universities, nonprofit economic development organizations and state governments to transfer advanced manufacturing technologies, processes, and methods as defined in §290.2 to small and medium sized firms. These technology transfer efforts focus on the continuous and incremental improvement of the target firms. The advanced manufacturing technology which is the focus of the

Centers is the subject of research in NIST's Automated Manufacturing Research Facility (AMRF). The core of AMRF research has principally been applied in discrete part manufacturing, including electronics, composites, plastics, and metal parts fabrication and assembly. Centers will be afforded the opportunity for interaction with the AMRF and will be given access to reasearch projects and results to strengthen their technology transfer. Where elements of a solution are available from an existing source, they should be employed. Where private-sector consultants who can meet the needs of a small- or medium-sized manufacturer are available, they should handle the task. Each Center should bring to bear the technology expertise described in §290.3(d) to assist small- and medium-sized manufacturing firms in adopting advanced manufacturing technology.

(b) *Program objective.* The objective of the NIST Manufacturing Technology Centers is to enhance productivity and technological performance in United States manufacturing. This will be accomplished through:

(1) The transfer of manufacturing technology and techniques developed at NIST to Centers and, through them, to manufacturing companies throughout the United States;

(2) The participation of individuals from industry, universities, State governments, other Federal agencies, and, when appropriate, NIST in cooperative technology transfer activities;

(3) Efforts to make new manufacturing technology and processes usable by United States-based small- and medium-sized companies;

(4) The active dissemination of scientific, engineering, technical, and management information about manufacturing to industrial firms, including small- and medium-sized manufacturing companies; and

(5) The utilization, when appropriate, of the expertise and capability that exists in Federal laboratories other than NIST.

(c) *Center activities.* The activities of the Centers shall include:

(1) The establishment of automated manufacturing systems and other advanced production technologies based on research by NIST and other Federal laboratories for the purpose of demonstrations and technology transfer;

(2) The active transfer and dissemination of research findings and Center expertise to a wide range of companies and enterprises, particularly small- and medium-sized manufacturers; and

(3) Loans, on a selective, short-term basis, of items of advanced manufacturing equipment to small manufacturing firms with less than 100 employees.

(d) *Center organization and operation.* Each Center will be organized to transfer advanced manufacturing technology to small and medium sized manufacturers located in its service region. Regional Centers will be established and operated via cooperative agreements between NIST and the award-receiving organizations. Individual awards shall be decided on the basis of merit review, geographical diversity, and the availability of funding.

(e) *Leverage.* The Centers program must concentrate on approaches which can be applied to other companies, in other regions, or by other organizations. The lessons learned in assisting a particular target firm should be documented in order to facilitate the use of those lessons by other target firms. A Center should build on unique solutions developed for a single company to develop techniques of broad applicability. It should seek wide implementation with well-developed mechanisms for distribution of results. Leverage is the principle of developing less resource-intensive methods of delivering technologies (as when a Center staff person has the same impact on ten firms as was formerly obtained with the resources used for one, or when a project once done by the Center can be carried out for dozens of companies by the private sector or a state or local organization.) Leverage does not imply a larger non-federal funding match (that is, greater expenditure of non-federal dollars for each federal dollar) but rather a greater impact per dollar.

(f) *Regional impact.* A new Center should not begin by spreading its resources too thinly over too large a geographic area. It should concentrate

first on establishing its structure, operating style, and client base within a manageable service area.

§ 290.4 Terms and schedule of financial assistance.

(a) NIST may provide financial support to any Center for a period not to exceed six years, subject to the availability of funding and continued satisfactory performance. Awards under this program shall be subject to all Federal and Departmental regulations, policies, and procedures applicable to Federal assistance awards. NIST may not provide more than 50 percent of the capital and annual operating and maintenance required to create and maintain such Center. Allowable capital costs may be treated as an expense in the year expended or obligated.

(b) *NIST contribution.* The funds provided by NIST may be used for capital and operating and maintenance expenses. Each Center will operate on one-year, annually renewable cooperative agreements, contingent upon successful completion of informal annual reviews. Funding can not be provided after the sixth year of support. A formal review of each Center will be conducted during its third year of operation by an independent Merit Review Panel in accordance with § 290.8 of these procedures. Centers will be required to demonstrate that they will be self-sufficient by the end of six years of operation. The amount of NIST investment in each Center will depend upon the particular requirements, plans, and performance of the Center, as well as the availability of NIST funds. NIST may support the budget of each Center on a matching-funds basis not to exceed the Schedule of Financial Assistance outlined in Table 1. The remaining portion of the Center's funding shall be provided by the host organization.

TABLE 1.—SCHEDULE OF NIST MATCHING FUNDS

Year of center operation	Maximum NIST share
1–3	½
4	⅖
5–6	⅓

(c) *Host contribution.* The host organization may count as part of its share:

(1) Dollar contributions from state, county, city, industrial, or other sources;

(2) Revenue from licensing and royalties;

(3) Fees for services performed,

(4) In-kind contributions of full-time personnel,

(5) In-kind contribution of part-time personnel, equipment, software, rental value of centrally located space (office and laboratory) and other related contributions up to a maximum of one-half of the host's annual share. Allowable capital expenditures may be applied in the award year expended or in subsequent award years.

[55 FR 38275, Sept. 17, 1990, as amended at 59 FR 22505, May 2, 1994]

§ 290.5 Basic proposal qualifications.

(a) NIST shall designate each proposal which satisfies the qualifications criteria below as ''qualified proposal'' and subject the qualified proposals to a merit review. Applications which do not meet the requirements of this section will not receive further consideration.

(1) *Qualified organizations.* Any nonprofit institution, or group thereof, or consortium of nonprofit institutions, including entities which already exist or may be incorporated specifically to manage the Center.

(2) *Proposal format.* Proposals for Center Operating Awards shall:

(i) Be submitted with a Standard Form 424 to the above address;

(ii) *Not exceed 25 typewritten pages in length for the basic proposal document* (which must include the information requirements of paragraph (a)(3) of this section); it may be accompanied by additional appendices of relevant supplementary attachments and tabular material. Basic proposal documents which exceed 25 pages in length will not be qualified for further review.

(3) *Proposal requirements.* In order to be considered for a Center Operating Award, proposals must contain:

(i) A plan for the allocation of intellectual property rights associated with any invention or copyright which may result from the involvement in the

Center's technology transfer or research activities consistent with the conditions of § 290.9;

(ii) A statement which provides adequate assurances that the host organization will contribute 50 percent or more of the proposed Center's capital and annual operating and maintenance costs for the first three years and an increasing share for each of the following three additional years. Applicants should provide evidence that the proposed Center will be self-supporting after six years.

(iii) A statement describing linkages to industry, government, and educational organizations within its service region.

(iv) A statement defining the initial service region including a statement of the constituency to be served and the level of service to be provided, as well as outyear plans.

(v) A statement agreeing to focus the mission of the Center on technology transfer activities and not to exclude companies based on state boundaries.

(vi) A proposed plan for the annual evaluation of the success of the Center by the Program, including appropriate criteria for consideration, and weighting of those criteria.

(vii) A plan to focus the Center's technology emphasis on areas consistent with NIST technology research programs and organizational expertise.

(viii) A description of the planned Center sufficient to permit NIST to evaluate the proposal in accordance with § 290.6 of these procedures.

(b) [Reserved]

§ 290.6 Proposal evaluation and selection criteria.

(a) In making a decision whether to provide financial support, NIST shall review and evaluate all qualified proposals in accordance with the following criteria, assigning equal weight to each of the four categories.

(1) *Identification of target firms in proposed region.* Does the proposal define an appropriate service region with a large enough population of target firms of small- and medium-sized manufacturers which the applicant understands and can serve, and which is not presently served by an existing Center?

(i) *Market analysis.* Demonstrated understanding of the service region's manufacturing base, including business size, industry types, product mix, and technology requirements.

(ii) *Geographical location.* Physical size, concentration of industry, and economic significance of the service region's manufacturing base. Geographical diversity of Centers will be a factor in evaluation of proposals; a proposal for a Center located near an existing Center may be considered only if the proposal is unusually strong and the population of manufacturers and the technology to be addressed justify it.

(2) *Technology resources.* Does the proposal assure strength in technical personnel and programmatic resources, full-time staff, facilities, equipment, and linkages to external sources of technology to develop and transfer technologies related to NIST research results and expertise in the technical areas noted in these procedures?

(3) *Technology delivery mechanisms.* Does the proposal clearly and sharply define an effective methodology for delivering advanced manufacturing technology to small- and medium-sized manufacturers?

(i) *Linkages.* Development of effective partnerships or linkages to third parties such as industry, universities, nonprofit economic organizations, and state governments who will amplify the Center's technology delivery to reach a large number of clients in its service region.

(ii) *Program leverage.* Provision of an effective strategy to amplify the Center's technology delivery approaches to achieve the proposed objectives as described in § 290.3(e).

(4) *Management and financial plan.* Does the proposal define a management structure and assure management personnel to carry out development and operation of an effective Center?

(i) *Organizational structure.* Completeness and appropriateness of the organizational structure, and its focus on the mission of the Center. Assurance of full-time top management of the Center.

(ii) *Program management.* Effectiveness of the planned methodology of program management.

(iii) *Internal evaluation.* Effectiveness of the planned continuous internal evaluation of program activities.

(iv) *Plans for financial matching.* Demonstrated stability and duration of the applicant's funding commitments as well as the percentage of operating and capital costs guaranteed by the applicant. Identification of matching fund sources and the general terms of the funding commitments. Evidence of the applicant's ability to become self-sustaining in six years.

(v) *Budget.* Suitability and focus of the applicant's detailed one-year budget and six-year budget outline.

§ 290.7 Proposal selection process.

Upon the availability of funding to establish Regional Centers, the Director shall publish a notice in the FEDERAL REGISTER requesting submission of proposals from interested organizations. Appliclants will be given an established time frame, not less than 60 days from the publication date of the notice, to prepare and submit a proposal. The proposal evaluation and selection process will consist of four principal phases: Proposal qualification; Proposal review and selection of finalists; Finalist site visits; and, Award determination. Further descriptions of these phases are provided in the following:

(a) *Proposal qualification.* All proposals will be reviewed by NIST to assure compliance with §290.5 of these procedures. Proposals which satisfy these requirements will be designated qualified proposals; all others will be disqualified at this phase of the evaluation and selection process.

(b) *Proposal review and selection of finalists.* The Director of NIST will appoint an evaluation panel to review and evaluate all qualified proposals in accordance with the criteria set forth in section 290.6 of these procedures, assigning equal weight to each of the four categories. From the qualified proposals, a group of finalists will be selected based on this review.

(c) *Finalist site visits.* NIST representatives will visit each finalist organization. Finalists will be reviewed and assigned numeric scores using the criteria set forth in §290.6 of these procedures assigning equal weight to each of the four categories. NIST may enter into negotiations with the finalists concerning any aspect of their proposal.

(d) *Award determination.* The Director of NIST or his designee shall select awardees for Center Operating Awards based upon the rank order of applicants, the need to assure appropriate regional distribution, and the availability of funds. Upon the final award decision, a notification will be made to each of the proposing organizations.

§ 290.8 Reviews of centers.

(a) *Overview.* Each Center will be reviewed at least annually, and at the end of its third year of operation according to the procedures and criteria set out below. There will be regular management interaction with NIST and the other Centers for the purpose of evaluation and program shaping. Centers are encouraged to try new approaches, must evaluate their effectiveness, and abandon or adjust those which do not have the desired impact.

(b) *Annual reviews of centers.* Centers will be reviewed annually as part of the funding renewal process using the criteria set out in §290.8(d). The funding level at which a Center is renewed is contingent upon a positive program evaluation and will depend upon the availability of federal funds and on the Center's ability to obtain suitable match, as well as on the budgetary requirements of its proposed program. Centers must continue to demonstrate that they will be self-supporting after six years.

(c) *Third year review of centers.* Each host receiving a Center Operating Award under these procedures shall be evaluated during its third year of operation by a Merit Review Panel appointed by the Secretary of Commerce. Each such Merit Review Panel shall be composed of private experts, none of whom shall be connected with the involved Center, and Federal officials. An official of NIST shall chair the panel. Each Merit Review Panel shall measure the involved Center's performance against the criteria set out in §290.8(d). The Secretary shall not provide funding for the fourth through the sixth years of such Center's operation unless the evaluation is positive on all

grounds. As a condition of receiving continuing funding, the Center must show evidence at the third year review that they are making substantial progress toward self-sufficiency. If the evaluation is positive and funds are available, the Secretary of Commerce may provide continued funding through the sixth year at declining levels, which are designed to insure that the Center no longer needs financial support from NIST by the seventh year. In no event shall funding for a Center be provided by the NIST Manufacturing Technology Centers Program after the sixth year of support.

(d) *Criteria for annual and third year reviews.* Centers will be evaluated under the following criteria in each of the annual reviews, as well as the third year review:

(1) The program objectives specified in § 290.3(b) of these procedures;

(2) Funds-matching performance;

(3) The extent to which the target firms have successfully implemented recently developed or currently developed advanced manufacturing technology and techniques transferred by the Center;

(4) The extent to which successes are properly documented and there has been further leveraging or use of a particular advanced manufacturing technology or process;

(5) The degree to which there is successful operation of a network, or technology delivery mechanism, involving the sharing or dissemination of information related to manufacturing technologies among industry, universities, nonprofit economic development organizations and state governments.

(6) The extent to which the Center can increasingly develop continuing resources—both technological and financial—such that the Centers are finally financially self-sufficient.

§ 290.9 Intellectual property rights.

(a) Awards under the Program will follow the policies and procedures on ownership to inventions made under grants and cooperative agreements that are set out in Public Law 96–517 (35 U.S.C. chapter 18), the Presidential Memorandum on Government Patent Policy to the Heads of Executive Departments and Agencies Dated February 18, 1983, and part 401 of title 37 of the Code of Federal Regulations, as appropriate. These policies and procedures generally require the Government to grant to Centers selected for funding the right to elect to obtain title to any invention made in the course of the conduct of research under an award, subject to the reservation of a Government license.

(b) Except as otherwise specifically provided for in an Award, Centers selected for funding under the Program may establish claim to copyright subsisting in any data first produced in the performance of the award. When claim is made to copyright, the funding recipient shall affix the applicable copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship to the data when and if the data are delivered to the Government, are published, or are deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software, the funding recipient shall grant to the Government, and others acting on its behalf, a paid up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the funding recipient shall grant to the Government, and others acting on its behalf, a paid up, nonexclusive, irrevocable, worldwide license for all such computer software to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government.

PART 291—MANUFACTURING EXTENSION PARTNERSHIP; ENVIRONMENTAL PROJECTS

Sec.

AUTHORITY: 15 U.S.C. §272(b)(1) and (c)(3) and §2781.

SOURCE: 60 FR 4082, Jan. 20, 1995, unless otherwise noted.

§291.1 Program description.

(a) In accordance with the provisions of the National Institute of Standards and Technology Act (15 U.S.C. §272(b)(1) and (c)(3) and §2781), as amended, NIST will provide financial assistance to integrate environmentally-related services and resources into the national manufacturing extension system. This assistance will be provided by NIST often in cooperation with the EPA. Under the NIST Manufacturing Extension Partnership (MEP), NIST will periodically make merit-based awards to existing MEP manufacturing extension affiliates for integration of environmental services into extension centers and to non-profit organizations for development of environmentally-related tools and techniques. In addition, NIST will initiate pilot centers providing environmental information for specific industrial sectors to be specified in solicitations. MEP assumes a broad definition of manufacturing, and recognizes a wide range of technology and concepts, including durable goods production; chemical, biotechnology, and other materials processing; electronic component and system fabrication; and engineering services associated with manufacturing, as lying within the definition of manufacturing.

(b) *Announcements of solicitations.* Announcements of solicitations will be made in the Commerce Business Daily. Specific information on the level of funding available and the deadline for proposals will be contained in that announcement. In addition, any specific industry sectors or types of tools and techniques to be focused on will be specified in the announcement.

(c) *Proposal workshops.* Prior to an announcement of solicitation, NIST may announce opportunities for potential applicants to learn about these projects through workshops. The time and place of the workshop(s) will be contained in a Commerce Business Daily announcement.

(d) *Indirect costs.* The total dollar amount of the indirect costs proposed in an application under this program must not exceed the indirect cost rate negotiated and approved by a cognizant Federal agency prior to the proposed effective date of the award or 100 percent of the total proposed direct costs dollar amount in the application, whichever is less.

(e) *Proposal format.* The Proposal must not exceed 20 typewritten pages in length for integration proposals. Proposals for tools and techniques projects and national information centers must not exceed 30 pages in length. The proposal must contain both technical and cost information. The Proposal page count shall include every page, including pages that contain words, table of contents, executive summary, management information and qualifications, resumes, figures, tables, and pictures. All proposals shall be printed such that pages are single-sided, with no more than fifty-five (55) lines per page. Use 21.6 x 27.9 cm (8½″ x 11″) paper or A4 metric paper. Use an easy-to-read font of not more than about 5 characters per cm (fixed pitch font of 12 or fewer characters per inch or proportional font of point size 10 or larger). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left and right) must be at least 2.5 cm. (1″). The applicant may submit a separately bound document of appendices, containing letters of support for the Basic Proposal. The basic proposal should be self-contained and not rely on the appendices for meeting criteria. Excess pages in the Proposal will not be considered in the evaluation. Applicants must submit one signed original plus six copies of the proposal along with Standard Form 424, 424A (Rev 4/92) and Form CD–511.

(f) *Content of basic proposal.* The Basic Proposal must, at a minimum, include the following:

(1) An executive summary summarizing the planned project consistent with the Evaluation Criteria stated in this notice.

(2) A description of the planned project sufficient to permit evaluation of the proposal in accordance with the proposal Evaluation Criteria stated in this notice.

(3) A budget for the project which identifies all sources of funds and which breaks out planned expenditures by both activity and object class (e.g., personnel, travel, etc.).

(4) A description of the qualifications of key personnel who will be assigned to work on the proposed project.

(5) A statement of work that discusses the specific tasks to be carried out, including a schedule of measurable events and milestones.

(6) A Standard Form 424, 424A (Rev 4–92) prescribed by the applicable OMB circular and Form CD–511, Certification Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying. SF–424, 424A (Rev 4–92) and Form CD–511 will not be considered part of the page count of the Basic Proposal.

(7) The application requirements and the standard form requirements have been approved by OMB (OMB Control Number 0693–0010, 0348–0043 and 0348–0044).

(g) *Applicable federal and departmental guidance.* This includes: Administrative Requirements, Cost Principles, and Audits. [Dependent upon type of Recipient organization: nonprofit, for-profit, state/local government, or educational institution]

(1) *Nonprofit organizations.*

(i) OMB Circular A–110—Uniform Administrative Requirements of Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(ii) OMB Circular A–122—Cost Principles for Nonprofit Organizations.

(iii) 15 CFR part 29b—Audit Requirements for Institutions of Higher Education and Other Nonprofit Organizations [implements OMB Circular A–133—Audits for Institutions of Higher Education and Other Nonprofit Organizations].

(2) *State/local governments.*

(i) 15 CFR part 24—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

(ii) OMB Circular A–87—Cost Principles for State and Local Governments.

(iii) 15 CFR part 29a—Audit Requirements for State and Local Governments [implements OMB Circular A–128—Audit of State and Local Governments].

(3) *Educational institutions.*

(i) OMB Circular A–110—Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(ii) OMB Circular A–21—Cost Principles for Educational Institutions.

(iii) 15 CFR part 29b—Audit Requirements for Institutions of Higher Education and Other Nonprofit Organizations [implements OMB Circular A–133—Audits for Institutions of Higher Education and Other Nonprofit Organizations].

§ 291.2 Environmental integration projects.

(a) *Eligibility criteria.* Eligible applicants for these projects are manufacturing extension centers or state technology extension programs which at the time of solicitation have grants, cooperative agreements or contracts with the NIST Manufacturing Extension Partnership. Only one proposal per organization per solicitation is permitted in this category.

(b) *Project objective.* The purpose of these projects is to support the integration of environmentally-focused technical assistance, and especially pollution prevention assistance, for smaller manufacturers into the broader services provided by existing MEP manufacturing extension centers. Proposers are free to structure their project in whatever way will be most effective and efficient in increasing the ability of the center to deliver high quality environmental and pollution prevention technical assistance (either directly or in partnership with other organizations). Following are some examples of purposes for which these funds could be used. This list is by no means meant to be all inclusive. A center might propose a set of actions encompassing several of these examples as well as others.

(1) *Environmental needs assessment.* Detailed assessment of the environmentally-related technical assistance needs of manufacturers within the state or region of the manufacturing extension center. This would be done as

part of a broader plan to incorporate environmentally related services into the services of the manufacturing extension center. The center might propose to document its process and findings so that other centers may learn from its work.

(2) *Partnership with another organization.* The center might propose to partner with an existing organization which is providing environmentally-focused technical assistance to manufacturers. The partnership would lead to greater integration of service delivery through joint technical assistance projects and joint training.

(3) *Accessing private-sector environmental resources.* The center might propose to increase it's ability to access environmental technical services for smaller manufacturers from environmental consultants or environmental firms.

(4) *Training of field engineers/agents in environmental topics.* Funding for training which empowers the field engineer/agent with the knowledge needed to recognize potential environmental, and especially pollution prevention, problems and opportunities. In addition, training might be funded which empowers the field engineer/agent with the knowledge needed to make appropriate recommendations for solutions or appropriate referrals to other sources of information or expertise. The over-arching goal is for the field engineer/agent to enable the manufacturer to be both environmentally clean and competitive.

(5) *Access to environmentally related information or expertise.* A center might propose to fund access to databases or other sources of environmentally-related information or expertise which might be necessary to augment the environmentally focused activities of the manufacturing extension center.

(6) *Addition of environmentally focused staff.* It may be necessary for manufacturing extension centers to have an environmental program manager or lead field engineer/agent with environmental training and experience. Funds could be requested to hire this person. However, the proposer would have to demonstrate a clear and reasonable plan for providing for the support of this person after the funds provided under this project are exhausted since no commitment is being made to ongoing funding.

(c) *Award period.* Projects initiated under this category may be carried out over multiple years. The proposer should include optional second and third years in their proposal. Proposals selected for award may receive one, two or three years of funding from currently available funds at the discretion of DOC. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. A separate cooperative agreement will be written with winning applicants. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC. It is anticipated that successful projects will be given the opportunity to roll the funding for these efforts into the base funding for the extension center. Such a roll-over will be based on a performance review and the availability of funds.

(d) *Matching requirements.* No matching funds are required for these proposals. However, the presence of matching funds (cash and in-kind) will be considered in the evaluation under the Financial Plan criteria.

(e) *Environmental integration projects evaluation criteria.* In most solicitations, preference will be given to projects which are focused on a single industry sector. This is desired to build on the expertise and resources which are being built in tools and resources projects in these industry sectors. Industry focus will be specified in the solicitation announcement. However, actual services need not be limited exclusively to this sector. In addition preference may be given to extension centers which do not have extensive environmentally-related services already in place. In addition to these preferences, the criteria for selection of awards will be as follows in descending order of importance:

(1) *Demonstrated commitment to incorporating environmentally related services.* The extension center must demonstrate its commitment to incorporate environmentally-related technical services into its overall manufacturing extension services even after

funding for this project is exhausted. It is not the objective of this effort to establish completely autonomous environmentally focused extension centers. Rather, the goal is to ensure that such services are integrated directly with general manufacturing extension services focused on competitiveness. The center must demonstrate that such integration will take place. Factors that may be considered include: The amount of matching funds devoted to the efforts proposed as demonstration of the center's commitment to the activity; indication that environmental services are a significant aspect of the organization's long range planning; strength of commitment and plans for continuing service beyond funding which might be awarded through this project; the degree to which environmental services will become an integral part of each field engineers' portfolio of services; the level of current or planned education and training of staff on relevant environmental issues; and the extent of environmentally related information and expert resources which will be easily accessible by field engineers.

(2) *Demonstrated understanding of the environmentally related technical assistance needs of manufacturers in the target population.* Target population must be clearly defined. The manufacturing center must demonstrate that it understands the populations environmentally related needs or include a coherent methodology for identifying those needs. The proposal should show that the efforts being proposed will enable the center to better meet those needs. Factors that may be considered include: A clear definition of the target population, its size and demographic characteristics; demonstrated understanding of the target population's environmental technical assistance needs or a plan to develop this understanding; and appropriateness of the size of the target population and the anticipated impact for the proposed expenditure.

(3) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are providing high quality environmentally-related services to manufacturers in the same target population or which have relevant resources which can be of assistance in the proposed effort. If no such organizations exist, the proposal should build the case that there are no such organizations. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication of services in providing assistance to small and medium-sized manufacturers. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant for providing technology assistance related services to the target population; adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities; and that the proposed activity does not duplicate existing services or resources.

(4) *Program evaluation:* The applicant should specify plans for evaluation of the effectiveness of the proposed program and for ensuring continuous improvement of program activities. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and ''customer satisfaction'' measures of performance.

(5) *Management experience and plans.* Applicants should specify plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; appropriateness of the organizational approach for carrying out the proposed activity; evidence of involvement and support by private industry.

(6) *Financial plan:* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the

cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget both in income and expenses; strength of commitment and amount of the proposer's cost share, if any; effectiveness of management plans for control of budget; appropriateness of matching contributions; and plans for maintaining the program after the cooperative agreement has expired.

§ 291.3 Environmental tools and techniques projects.

(a) *Eligibility criteria.* Eligible applicants for these projects include all nonprofit organizations including universities, community colleges, state governments, state technology programs and independent nonprofit organizations. Organizations may submit multiple proposals under this category in each solicitation for unique projects.

(b) *Project objective.* The purpose of these projects is to support the initial development and implementation of tools or techniques which will aide manufacturing extension organizations in providing environmentally-related services to smaller manufacturers and which may also be of direct use by the smaller manufacturers themselves. Specific industry sectors to be addressed and sub-categories of tools and techniques may be specified in solicitations. These sectors or sub-categories will be specified in the solicitation announcement. Examples of tools and techniques include, but are not limited to, manufacturing assessment tools, environmental benchmarking tools, training delivery programs, electronically accessible environmental information resources, environmental demonstration facilities, software tools, etc. Projects must be completed within the scope of the effort proposed and should not require on-going federal support.

(c) *Award period.* Projects initiated under this category may be carried out over up to three years. Proposals selected for award will receive all funding from currently available funds. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC.

(d) *Matching requirements.* No matching funds are required for these proposals. However, the presence of matching funds (cash and in-kind) will be considered in the evaluation under the Financial Plan criteria.

(e) *Environmental tools and techniques projects evaluation criteria.* Proposals from applicants will be evaluated and rated on the basis of the following criteria listed in descending order of importance:

(1) *Demonstrated understanding of the environmentally-related technical assistance needs of manufacturers and technical assistance providers in the target population.* Target population must be clearly defined. The proposal must demonstrate that it understands the population's environmentally related tool or technique needs. The proposal should show that the efforts being proposed meet the needs identified. Factors that may be considered include: A clear definition of the target population, size and demographic distribution; demonstrated understanding of the target population's environmental tools or techniques needs; and appropriateness of the size of the target population and the anticipated impact for the proposed expenditure.

(2) *Technology and information sources.* The proposal must delineate the sources of technology and/or information which will be used to create the tool or resource. Sources may include those internal to the center (including staff expertise) or from other organizations. Factors that may be considered include: Strength of core competency in the proposed area of activity; and demonstrated access to relevant technical or information sources external to the organization.

(3) *Degree of integration with the manufacturing extension partnership.* The proposal must demonstrate that the tool or resource will be integrated into and will be of service to the NIST Manufacturing Extension Centers. Factors that may be considered include: Ability to access the tool or resource especially for MEP extension centers; methodology for disseminating or promoting use of the tool or technique especially within the MEP system; and

demonstrated interest in using the tool or technique especially by MEP extension centers.

(4) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are developing or have expertise on similar tools or techniques. If no such organizations exist, the proposal should show that this the case. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant to the proposed project; Adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities; and that the proposed activity does not duplicate existing services or resources.

(5) *Program evaluation.* The applicant should specify plans for evaluation of the effectiveness of the proposed tool or technique and for ensuring continuous improvement of the tool. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and ''customer satisfaction'' measures of performance.

(6) *Management experience and plans.* Applicants should specify plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(7) *Financial plan:* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considerable include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposers's cost share, if any; effectiveness of management plans for control of budget appropriateness of matching contributions; and plan for maintaining the program after the cooperative agreement has expired.

§ 291.4 National industry-specific pollution prevention and environmental compliance resource centers.

(a) *Eligibility criteria.* Eligible applicants for these projects include all nonprofit organizations including universities, community colleges, state governments, state technology programs and independent nonprofit organizations. Only one proposal per organization is permitted in this category.

(b) *Project objective.* These centers will provide easy access to relevant, current, reliable and comprehensive information on pollution prevention opportunities, regulatory compliance and technologies and techniques for reducing pollution in the most competitive manner for a specific industry sector or industrial process. The sector or industrial process to be addressed will be specified in the solicitation. The center will enhance the ability of small businesses to implement risk based pollution prevention alternatives to increase competitiveness and reduce adverse environmental impacts. The center should use existing resources, information and expertise and will avoid duplication of existing efforts. The information provided by the center will create links between relevant EPA Pollution Prevention programs, EPA and other technical information, NIST manufacturing extension efforts, EPA regulation and guidance, and state requirements. The center will emphasize pollution prevention methods as the principal means to both comply with government regulations and enhance competitiveness.

(c) *Project goal.* To improve the environmental and competitive performance of smaller manufacturers by:

(1) Enhancing the national capability to provide pollution prevention and

regulatory requirements information (federal, state and local) to specific industries.

(2) Providing easy access to relevant and reliable information and tools on pollution prevention technologies and techniques that achieve manufacturing efficiency and enhanced competitiveness with reduced environmental impact.

(3) Providing easy access to relevant and reliable information and tools to enable specific industries to achieve the continued environmental improvement to meet or exceed compliance requirements.

(d) *Project customers.* (1) The customers for this center will be the businesses in the industrial sector or businesses which use the industrial process specified as the focus for the solicitation. In addition, consultants providing services to those businesses, the NIST Manufacturing Extension Centers, and federal state and local programs providing technical, pollution prevention and compliance assistance.

(2) The center should assist the customer in choosing the most cost- effective, environmentally sound options or practices that enhance the company's competitiveness. Assistance must be accessible to all interested customers. The center, wherever feasible, shall use existing materials and information to enhance and develop the services to its customers. The centers should rarely, if ever, perform research, but should find and assimilate data and information produced by other sources. The center should not duplicate any existing distribution system. The center should distribute and provide information, but should not directly provide on-site assistance to customers. Rather, referrals to local technical assistance organizations should be given when appropriate. Information would likely be available through multiple avenues such as phone, fax, electronically accessible data bases, printed material, networks of technical experts, etc.

(e) *Award period.* The pilot initiated under this category may be carried out over multiple years. The proposers should include optional second and third years in their proposal. Proposals selected for award may receive one, two or three years of funding from currently available finds at the discretion of DOC. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC. Successful centers may be given an opportunity to receive continuing funding as a NIST manufacturing center after the expiration of their initial cooperative agreement. Such a roll-over will be based upon the performance of the center and availability of funding.

(f) *Matching requirements.* A matching contribution from each applicant will be required. NIST may provide financial support up to 50% of the total budget for the project. The applicant's share of the budget may include dollar contributions from state, county, industrial or other non-federal sources and non-federal in-kind contributions necessary and reasonable for proper accomplishment of project objectives.

(g) *Resource center evaluation criteria.* Proposals from applicants will be evaluated and rated on the basis of the following criteria listed in descending order of importance:

(1) *Demonstrated understanding of the environmentally-related information needs of manufacturers and technical assistance providers in the target population.* Understanding the environmentally-related needs of the target population (i.e., customers) is absolutely critical to the success of such a resource center. Factors that may be considered include: A clear definition of the target population, size and demographic distribution; demonstrated understanding of the target population's environmentally-related information needs or a clear plan for identifying those customer needs; and methodologies for continually improving the understanding of the target population's environmentally-related information needs.

(2) *Delivery mechanisms.* The proposal must set forth clearly defined, effective mechanisms for delivery of services to target population. Factors that may be considered include: Potential effectiveness and efficiency of proposed delivery systems; and demonstrated capacity to

form the effective linkages and partnerships necessary for success of the proposed activity.

(3) *Technology and information sources.* The proposal must delineate the sources of information which will be used to create the informational foundation of the resource center. Sources may include those internal to the Center (including staff expertise), but it is expected that many sources will be external. Factors that may be considered include: Strength of core competency in the proposed area of activity; demonstrated access to relevant technical or information sources external to the organization.

(4) *Degree of integration with the manufacturing extension partnership and other technical assistance providers.* The proposal must demonstrate that the source center will be integrated into the system of services provided by the NIST Manufacturing Extension Partnership and other technical assistance providers. Factors that may be considered include: Ability of the target population including MEP Extension Centers to access the resource center; and methodology for disseminating or promoting use of the resource center especially within the MEP system.

(5) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are developing or have expertise on similar tools or techniques. If no such organizations exist, the proposal should show that this is the case. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant to the proposed project; and adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities.

(6) *Program evaluation.* The applicant should specify plans for evaluation of the effectiveness of the proposed resource center and for ensuring continuous improvement. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and ''customer satisfaction'' measures of performance; and the proposer's plan must include documentation, analysis of the results, and must show how the results can be used in improving the resource center.

(7) *Management experience and Plans.* Applicants should specify Plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications and experience of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(8) *Financial plan.* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposer's *cost share*; effectiveness of management plans for control of the budget; and appropriateness of matching contributions.

§ 291.5 Proposal selection process.

The proposal evaluation and selection process will consist of three principal phases: Proposal qualification; proposal review and selection of finalists; and award determination.

(a) *Proposal qualification.* All proposals will be reviewed by NIST to assure compliance with the proposal content and other basic provisions of this notice. Proposals which satisfy these requirements will be designated qualified proposals; all others will be disqualified at this phase of the evaluation and selection process.

(b) *Proposal review and selection of finalists.* NIST will appoint an evaluation panel composed of NIST and in some

cases other federal employees to review and evaluate all qualified proposals in accordance with the evaluation criteria and values set forth in this notice. A site visit may be required to make full evaluation of a proposal. From the qualified proposals, a group of finalists will be numerically ranked and recommended for award based on this review.

(c) *Award determination.* The Director of the NIST, or her/his designee, shall select awardees based on total evaluation scores, geographic distribution, and the availability of funds. All three factors will be considered in making an award. Upon the final award decision, a notification will be made to each of the proposing organizations.

§ 291.6 Additional requirements; Federal policies and procedures.

Recipients and subrecipients are subject to all Federal laws and Federal and Department of Commerce policies, regulations, and procedures applicable to Federal financial assistance awards.

PART 292—MANUFACTURING EXTENSION PARTNERSHIP; INFRASTRUCTURE DEVELOPMENT PROJECTS

Sec.

AUTHORITY: 15 U.S.C. 272 (b)(1) and (c)(3) and 278l.

SOURCE: 60 FR 44751, Aug. 29, 1995, unless otherwise noted.

§ 292.1 Program description.

(a) *Purpose.* In accordance with the provisions of the National Institute of Standards and Technology Act (15 U.S.C. 272 (b)(1) and (c)(3) and 278l), as amended, NIST will provide financial assistance to develop the infrastructure of the national manufacturing extension system. Under the NIST Manufacturing Extension Partnership (MEP), NIST will periodically make merit-based awards to develop and deploy training capability and technical tools, techniques, practices, and analyses. In addition, NIST will develop and implement information infrastructure services and pilots. MEP assumes a broad definition of manufacturing, and recognizes a wide range of technology and concepts, including durable goods production; chemical, biotechnology, and other materials processing; electronic component and system fabrication; and engineering services associated with manufacturing, as lying within the definition of manufacturing.

(b) *Announcements of solicitations.* Announcements of solicitations will be made in the Commerce Business Daily. Specific information on the level of funding available and the deadline for proposals will be contained in that announcement. In addition, any specific industry sectors or types of tools and techniques to be focused on will be specified in the announcement, as well as any further definition of the selection criteria.

(c) *Proposal workshops.* Prior to an announcement of solicitation, NIST may announce opportunities for potential applicants to learn about these projects through workshops. The time and place of the workshop(s) will be contained in a Commerce Business Daily announcement.

(d) *Indirect costs.* The total dollar amount of the indirect costs proposed in an application under this program must not exceed the indirect cost rate negotiated and approved by a cognizant Federal agency prior to the proposed effective date of the award or 100 percent of the total proposed direct costs dollar amount in the application, whichever is less.

(e) *Proposal format.* The proposal must contain both technical and cost information. The proposal page count shall include every page, including pages that contain words, table of contents, executive summary, management information and qualifications, resumes, figures, tables, and pictures. All proposals shall be printed such that pages are single-sided, with no more than fifty-five (55) lines per page. Use 21.6×27.9 cm (8½″×11″) paper or A4 metric paper. Use an easy-to-read font of not more than about 5 characters per

cm (fixed pitch font of 12 or fewer characters per inch or proportional font of point size 10 or larger). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left and right) must be at lease 2.5 cm. (1″). Length limitations for proposals will be specified in solicitations. The applicant may submit a separately bound document of appendices, containing letters of support for the proposal. The proposal should be self-contained and not rely on the appendices for meeting criteria. Excess pages in the proposal will not be considered in the evaluation. Applicants must submit one signed original plus six copies of the proposal and Standard Form 424, 424A, and 424B (Rev 4/92), Standard Form LLL, and Form CD–511. Applicants for whom the submission of six copies presents financial hardship may submit one original and two copies of the application.

(f) *Content of proposal.* (1) The proposal must, at a minimum, include the following:

(i) An executive summary summarizing the planned project consistent with the Evaluation Criteria stated in this part.

(ii) A description of the planned project sufficient to permit evaluation of the proposal in accordance with the proposal Evaluation Criteria stated in this part.

(iii) A budget for the project which identifies all sources of funds and which breaks out planned expenditures by both activity and object class (e.g., personnel, travel, etc.).

(iv) A description of the qualifications of key personnel who will be assigned to work on the proposed project.

(v) A statement of work that discusses the specific tasks to be carried out, including a schedule of measurable events and milestones.

(vi) A completed Standard Form 424, 424A, and 424B (Rev 4–92) prescribed by the applicable OMB circular, Standard Form LLL, and Form CD–511, Certification Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying. SF–424, 424A, 424B (Rev 4–92), SF–LLL, and Form CD–511 will not be considered part of the page count of the proposal.

(2) The application requirements and the standard form requirements have been approved by OMB (OMB Control Number 0693–0005, 0348–0043 and 0348–0044).

(g) *Applicable federal and departmental guidance.* The Administrative Requirements, Cost Principles, and Audits are dependent upon type of Recipient organization as follows:

(1) *Nonprofit organizations.* (i) OMB Circular A–110—Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(ii) OMB Circular A–122—Cost Principles for Nonprofit Organizations.

(iii) 15 CFR Part 29b—Audit Requirements for Institutions of Higher Education and Other Nonprofit Organizations (implements OMB Circular A–133—Audits for Institutions of Higher Education and Other Nonprofit Organizations).

(2) *State/local governments.* (i) 15 CFR Part 24—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

(ii) OMB Circular A–87—Cost Principles for State and Local Governments.

(iii) 15 CFR Part 29a—Audit Requirements for State and Local Governments (implements OMB Circular A–128—Audit of State and Local Governments).

(3) *Educational institutions.* (i) OMB Circular A–110—Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(ii) OMB Circular A–21—Cost Principles for Educational Institutions.

(iii) 15 CFR Part 29b—Audit Requirements for Institutions of Higher Education and Other Nonprofit Organizations (implements OMB Circular A–133—Audits for Institutions of Higher Education and Other Nonprofit Organizations).

(4) *For-profit organizations.* (i) OMB Circular A–110—Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

(ii) 48 CFR Part 31—Federal Acquisition Regulation, Contract Cost Principles and Procedures.

(iii) 15 CFR Part 29b—Audit Requirements for Institutions of Higher Education and Other Nonprofit Organizations (implements OMB Circular A–133).

(h) *Availability of forms and circulars.* (1) Copies of forms referenced in this part may be obtained from the Manufacturing Extension Partnership, National Institute of Standards and Technology, Room C121, Building 301, Gaithersburg, MD 20899.

(2) Copies of OMB Circulars may be obtained from the Office of Administration, Publications Office, 725 17th St., NW, Room 2200, New Executive Office Building, Washington, DC 20503.

§ 292.2 Training development and deployment projects.

(a) *Eligibility criteria.* In general, eligible applicants for these projects include all for-profit and nonprofit organizations including universities, community colleges, state governments, state technology programs and independent nonprofit organizations. However, specific limitations on eligibility may be specified in solicitations. Organizations may submit multiple proposals under this category in each solicitation for unique projects.

(b) *Project objective.* The purpose of these projects is to support the development and deployment of training programs which will aid manufacturing extension organizations in providing services to smaller manufacturers. While primarily directed toward the field agents/engineers of the extension organizations, the training may also be of direct use by the smaller manufacturers themselves. Specific industry sectors to be addressed and sub-categories of training may be specified in solicitations. Examples of training topic areas include, but are not limited to, manufacturing assessment functions, business systems management, quality assurance assistance, and financial management activities. Examples of training program deployment include, but are not limited to, organization and conduct of training courses, development and conduct of train-the-trainer courses, preparations and delivery of distance learning activities, and preparation of self-learning and technical-guideline materials. Projects must be completed within the scope of the effort proposed and should not require on-going federal support.

(c) *Award period.* Projects initiated under this category may be carried out over a period of up to three years. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC.

(d) *Matching requirements.* Matching fund requirements for these proposals will be specified in solicitations including the breakdown of cash and in-kind requirements. For those projects not requiring matching funds, the presence of match will be considered in the evaluation under the Financial Plan criteria.

(e) *Training development and deployment projects evaluation criteria.* Proposals will be evaluated and rated on the basis of the following criteria listed in descending order of importance:

(1) *Demonstration that the proposed project will meet the training needs of technical assistance providers and manufacturers in the target population.* The target population must be clearly defined and the proposal must demonstrate that it understands the population's training needs within the proposed project area. The proposal should show that the efforts being proposed meet the needs identified. Factors that may be considered include: A clear definition of the target population, size and demographic distribution; demonstrated understanding of the target population's training needs; and appropriateness of the size of the target population and the anticipated impact for the proposed expenditure.

(2) *Development/deployment methodology and use of appropriate technology and information sources.* The proposal must describe the technical plan for the development or deployment of the training, including the project activities to be used in the training development/deployment and the sources of technology and/or information which will be used to create or deploy the

training activity. Sources may include those internal to the proposer or from other organizations. Factors that may be considered include: Adequacy of the proposed technical plan; strength of core competency in the proposed area of activity; and demonstrated access to relevant technical or information sources external to the organization.

(3) *Delivery and implementation mechanisms.* The proposal must set forth clearly defined, effective mechanisms for delivery and/or implementation of proposed services to the target population. The proposal also must demonstrate that training activities will be integrated into and will be of service to the NIST Manufacturing Extension Centers. Factors that may be considered include: Ease of access to the training activity especially for MEP extension centers; methodology for disseminating or promoting involvement in the training especially within the MEP system; and demonstrated interest in the training activity especially by MEP extension centers.

(4) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are developing or have expertise with similar training. If no such organizations exist, the proposal should show that this is the case. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant to the proposed project; adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities; and that the proposed activity does not duplicate existing services or resources.

(5) *Program evaluation.* The applicant should specify plans for evaluation of the effectiveness of the proposed training activity and for ensuring continuous improvement of the training. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and ''customer satisfaction'' measures of performance.

(6) *Management and organizational experience and plans.* Applicants should specify plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(7) *Financial plan.* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposer's cost share, if any; effectiveness of management plans for control of budget; appropriateness of matching contributions; and plan for maintaining the program after the cooperative agreement has expired.

§ 292.3 Technical tools, techniques, practices, and analyses projects.

(a) *Eligibility criteria.* In general, eligible applicants for these projects include all for profit and nonprofit organizations including universities, community colleges, state governments, state technology programs and independent nonprofit organizations. However, specific limitations on eligibility may be specified in solicitations. Organizations may submit multiple proposals under this category in each solicitation for unique projects.

(b) *Project objective.* The purpose of these projects is to support the initial development, implementation, and analysis of tools, techniques, and practices which will aid manufacturing extension organizations in providing services to smaller manufacturers and

which may also be of direct use by the smaller manufacturers themselves. Specific industry sectors to be addressed and sub-categories of tools, techniques, practices, and analyses may be specified in solicitations. Examples of tools, techniques, and practices include, but are not limited to, manufacturing assessment tools, benchmarking tools, business systems management tools, quality assurance assistance tools, financial management tools, software tools, practices for partnering, techniques for urban or rural firms, and comparative analysis of assessment methods. Projects must be completed within the scope of the effort proposed and should not require on-going federal support.

(c) *Award period.* Projects initiated under this category may be carried out over a period of up to three years. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC.

(d) *Matching requirements.* Matching fund requirements for these proposals will be specified in solicitations including the breakdown of cash and in-kind requirements. For those projects not requiring matching funds, the presence of match will be considered in the evaluation under the Financial Plan criteria.

(e) *Tools, techniques, practices, and analyses projects evaluation criteria.* Proposals from applicants will be evaluated and rated on the basis of the following criteria listed in descending order of importance:

(1) *Demonstration that the proposed project will meet the technical assistance needs of technical assistance providers and manufacturers in the target population.* Target population must be clearly defined. The proposal must demonstrate that it understands the population's tool or technique needs within the proposed project area. The proposal should show that the efforts being proposed meet the needs identified. Factors that may be considered include: A clear definition of the target population, size and demographic distribution; demonstrated understanding of the target population's tools or technique needs; and appropriateness of the size of the target population and the anticipated impact for the proposed expenditure.

(2) *Development methodology and use of appropriate technology and information sources.* The proposal must describe the technical plan for the development of the tool or resource, including the project activities to be used in the tool/resource development and the sources of technology and/or information which will be used to create the tool or resource. Sources may include those internal to the proposer or from other organizations. Factors that may be considered include: Adequacy of the proposed technical plan; strength of core competency in the proposed area of activity; and demonstrated access to relevant technical or information sources external to the organization.

(3) *Degree of integration with the manufacturing extension partnership.* The proposal must demonstrate that the tool or resource will be integrated into and will be of service to the NIST Manufacturing Extension Centers. Factors that may be considered include: Ability to access the tool or resource especially for MEP extension centers; methodology for disseminating or promoting use of the tool or technique especially within the MEP system; and demonstrated interest in using the tool or technique especially by MEP extension centers.

(4) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are developing or have expertise on similar tools, techniques, practices, or analyses. If no such organizations exist, the proposal should show that this is the case. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant to the proposed project; adequate linkages and partnerships with existing organizations and clear definition of those organizations' roles in the proposed activities; and that the proposed activity does not duplicate existing services or resources.

(5) *Program evaluation.* The applicant should specify plans for evaluation of the effectiveness of the proposed tool or technique and for ensuring continuous improvement of the tool. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and ''customer satisfaction'' measures of performance.

(6) *Management experience and plans.* Applicants should specify plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(7) *Financial plan.* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposer's cost share, if any; effectiveness of management plans for control of budget; appropriateness of matching contributions; and plan for maintaining the program after the cooperative agreement has expired.

§ 292.4 Information infrastructure projects.

(a) *Eligibility criteria.* In general, eligible applicants for these projects include all for profit and nonprofit organizations including universities, community colleges, state governments, state technology programs and independent nonprofit organizations. However, specific limitations on eligibility may be specified in solicitations. Organizations may submit multiple proposals under this category in each solicitation for unique projects.

(b) *Project objective.* The purpose of these projects is to support and act as a catalyst for the development and implementation of information infrastructure services and pilots. These projects will aid manufacturing extension organizations and smaller manufacturers in accessing the technical information they need or will accelerate the rate of adoption of electronic commerce. Specific industry sectors to be addressed or subcategories of information infrastructure projects include, but are not limited to, pilot demonstration of electronic data interchange in a supplier chain, implementation of an electronic information service for field engineers at MEP extension centers, and industry specific electronic information services for MEP centers and smaller manufacturers.

(c) *Award period.* Projects initiated under this category may be carried out over a period of up to three years. If an application is selected for funding, DOC has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of DOC.

(d) *Matching requirements.* Matching fund requirements for these proposals will be specified in solicitations including the breakdown of cash and in-kind requirements. For those projects not requiring matching funds, the presence of match will be considered in the evaluation under the Financial Plan criteria.

(e) *Information infrastructure projects evaluation criteria.* Proposals from applicants will be evaluated and rated on the basis of the following criteria listed in descending order of importance:

(1) *Demonstration that the proposed project will meet the need of the target customer base.* The target customer base must be clearly defined and, in general, will be technical assistance providers and/or smaller manufacturers. The proposal should demonstrate a clear understanding of the customer base's needs within the proposed project area. The proposal should also show that the efforts being proposed meet the needs

identified. Factors that may be considered include: A clear definition of the customer base, size and demographic distribution; demonstrated understanding of the customer base's needs within the project area; and appropriateness of the size of the customer base and the anticipated impact for the proposed expenditure.

(2) *Development plans and delivery/implementation mechanisms.* The proposal must set forth clearly defined, effective plans for the development, delivery and/or implementation of proposed services to the customer base. The proposal must delineate the sources of information which will be used to implement the project. Sources may include those internal to the center (including staff expertise) or from other organizations. Factors that may be considered include: Adequacy of plans; potential effectiveness and efficiency of proposed delivery and implementation systems; demonstrated capacity to form effective linkages; partnerships necessary for success of the proposed activity; strength of core competency in the proposed area of activity; and demonstrated access to relevant technical or information sources external to the organization.

(3) *Coordination with other relevant organizations.* Wherever possible the project should be coordinated with and leverage other organizations which are developing or have expertise within the project area. In addition, the project should demonstrate that it does not duplicate efforts which already are being performed by the private sector without government support. Applicants will need to describe how they will coordinate to allow for increased economies of scale and to avoid duplication. If the proposer will not be partnering with any other organizations, then the proposal should clearly explain why the project will be more successful if implemented as proposed. A proposal which makes a credible case for why there are no, or very limited, partnerships will not be penalized in evaluation. Factors that may be considered include: Demonstrated understanding of existing organizations and resources relevant to the proposed project; Adequate linkages and partnerships with relevant existing organizations; clear definition of the roles of partnering organizations in the proposed activities; and that the proposed activity does not duplicate existing services or resources.

(4) *Management and organizational experience and plans.* Applicants should specify plans for proper organization, staffing, and management of the project. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(5) *Financial plan.* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and the ability of the project to continue after the cooperative agreement has expired without federal support. While projects that appear to require ongoing public support will be considered, in general, they will be evaluated lower than those which show a strong ability to become self-sufficient. Factors that may be considered include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposer's cost share, if any; effectiveness of management plans for control of budget; appropriateness of matching contributions; and plan for maintaining the program after the cooperative agreement has expired.

(6) *Evaluation.* The applicant should specify plans for evaluation of the effectiveness of the proposed project and for ensuring continuous improvement. Factors that may be considered include: Thoroughness of evaluation plans, including internal evaluation for management control, external evaluation for assessing outcomes of the activity, and ''customer satisfaction'' measures of performance.

§ 292.5 Proposal selection process.

The proposal evaluation and selection process will consist of three principal phases: Proposal qualifications; proposal review and selection of finalists; and award determination as follows:

(a) *Proposal qualification.* All proposals will be reviewed by NIST to assure compliance with the proposal content and other basic provisions of this part. Proposals which satisfy these requirements will be designated qualified proposals; all others will be disqualified at this phase of the evaluation and selection process.

(b) *Proposal review and selection of finalists.* NIST will appoint an evaluation panel to review and evaluate all qualified proposals in accordance with the evaluation criteria and values set forth in this part. Evaluation panels will consist of NIST employees and in some cases other federal employees or non-federal experts who sign non-disclosure agreements. A site visit may be required to make full evaluation of a proposal. From the qualified proposals, a group of finalists will be numerically ranked and recommended for award based on this review.

(c) *Award determination.* The Director of the NIST, or her/his designee, shall select awardees based on total evaluation scores, geographic distribution, and the availability of funds. All three factors will be considered in making an award. Upon the final award decision, a notification will be made to each of the proposing organizations.

§ 292.6 Additional requirements.

Federal policies and procedures. Recipients and subrecipients are subject to all Federal laws and Federal and Department of Commerce policies, regulations, and procedures applicable to Federal financial assistance awards.

PART 295—ADVANCED TECHNOLOGY PROGRAM

Subpart A—General

Sec.

Subpart B—Assistance to United States Industry-Led Joint Research and Development Ventures

Subpart C—Assistance to Single-Proposer U.S. Businesses

AUTHORITY: 15 U.S.C. 278n.

SOURCE: 55 FR 30145, July 24, 1990, unless otherwise noted.

Subpart A—General

§ 295.1 Purpose.

(a) The purpose of the Advanced Technology Program (ATP) is to assisted United States businesses to carry out research and development on high risk, high pay-off, emerging and enabling technologies. These technologies are:

(1) High risk, because the technical challenges make success uncertain;

(2) High pay-off, because when applied they offer significant benefits to the U.S. economy; and

(3) Emerging and enabling, because they offer wide breadth of potential application and form an important technical basis for future commercial applications.

(b) The rules in this part prescribe policies and procedures for the award of cooperative agreements under the Advanced Technology Program in

order to ensure the fair treatment of all proposals. While the Advanced Technology Program is authorized to enter into grants, cooperative agreements, and contracts to carry out its mission, the rules in this part address only the award of cooperative agreements. The Program employs cooperative agreements rather than grants because such agreements allow ATP to exercise appropriate management oversight of projects and also to link ATP-funded projects to ongoing R&D at the National Institute of Standards and Technology wherever such linkage would increase the likelihood of success of the project.

(c) In carrying out the rules in this part, the Program endeavors to put more emphasis on joint ventures and consortia with a broad range of participants, including large companies, and less emphasis on support of individual large companies.

[62 FR 64684, Dec. 9, 1997]

§ 295.2 Definitions.

(a) For the purposes of the ATP, the term *award* means Federal financial assistance made under a grant or cooperative agreement.

(b) The term *company* means a for-profit organization, including sole proprietors, partnerships, limited liability companies (LLCs), or corporations.

(c) The term *cooperative agreement* refers to a Federal assistance instrument used whenever the principal purpose of the relationship between the Federal Government and the recipient is the transfer of money, property, or services, or anything of value to the recipient to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal Government; and substantial involvement is anticipated between the executive agency, acting for the Federal Government, and the recipient during performance of the contemplated activity.

(d) The term *direct costs* means costs that can be identified readily with activities carried out in support of a particular final objective. A cost may not be allocated to an award as a direct cost if any other cost incurred for the same purpose in like circumstances has been assigned to an award as an indirect cost. Because of the diverse characteristics and accounting practices of different organizations, it is not possible to specify the types of costs which may be classified as direct costs in all situations. However, typical direct costs could include salaries of personnel working on the ATP project and associated reasonable fringe benefits such as medical insurance. Direct costs might also include supplies and materials, special equipment required specifically for the ATP project, and travel associated with the ATP project. ATP shall determine the allowability of direct costs in accordance with applicable Federal cost principles.

(e) The term *foreign-owned company* means a company other than a United States-owned company as defined in § 295.2(q).

(f) The term *grant* means a Federal assistance instrument used whenever the principal purpose of the relationship between the Federal Government and the recipient is the transfer of money, property, services, or anything of value to the recipient in order to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal Government; and no substantial involvement is anticipated between the executive agency, acting for the Federal Government, and the recipient during performance of the contemplated activity.

(g) The term *independent research organization* (IRO) means a nonprofit research and development corporation or association organized under the laws of any state for the purpose of carrying out research and development on behalf of other organizations.

(h) The term *indirect costs* means those costs incurred for common or joint objectives that cannot be readily identified with activities carried out in support of a particular final objective. A cost may not be allocated to an award as an indirect cost if any other cost incurred for the same purpose in like circumstances has been assigned to an award as a direct cost. Because of diverse characteristics and accounting

practices it is not possible to specify the types of costs which may be classified as indirect costs in all situations. However, typical examples of indirect costs include general administration expenses, such as the salaries and expenses of executive officers, personnel administration, maintenance, library expenses, and accounting. ATP shall determine the allowability of indirect costs in accordance with applicable Federal cost principles.

(i) The term *industry-led joint research and development venture* or *joint venture* means a business arrangement that consists of two or more separately-owned, for-profit companies that perform research and development in the project; control the joint venture's membership, research directions, and funding priorities; and share total project costs with the Federal government. The joint venture may include additional companies, independent research organizations, universities, and/or governmental laboratories (other than NIST) which may or may not contribute funds (other than Federal funds) to the project and perform research and development. A for-profit company or an independent research organization may serve as an Administrator and perform administrative tasks on behalf of a joint venture, such as handling receipts and disbursements of funds and making antitrust filings. The following activities are not permissible for ATP funded joint ventures:

(1) Exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service that is not reasonably required to conduct the research and development that is the purpose of such venture;

(2) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production or marketing by any person who is a party to such joint venture of any product, process, or service, other than the production or marketing of proprietary information developed through such venture, such as patents and trade secrets; and

(3) Entering into any agreement or engaging in any other conduct:

(i) To restrict or require the sale, licensing, or sharing of inventions or developments not developed through such venture, or

(ii) To restrict or require participation by such party in other research and development activities, that is not reasonably required to prevent misappropriation of proprietary information contributed by any person who is a party to such venture or of the results of such venture.

(j) The term *intellectual property* means an invention patentable under title 35, United States Code, or any patent on such an invention.

(k) The term *large business* for a particular ATP competition means any business, including any parent company plus related subsidiaries, having annual revenues in excess of the amount published by ATP in the relevant annual notice of availability of funds required by §295.7(a). In establishing this amount, ATP may consider the dollar value of the total revenues of the 500th company in Fortune Magazine's Fortune 500 listing.

(l) The term *matching funds or cost sharing* means that portion of project costs not borne by the Federal government. Sources of revenue to satisfy the required cost share include cash and in-kind contributions. Cash contributions can be from recipient, state, county, city, or other non-federal sources. In-kind contributions can be made by recipients or non-federal third parties (except subcontractors working on an ATP project) and include but are not limited to equipment, research tools, software, and supplies. Except as specified at §295.25, the value of in-kind contributions shall be determined in accordance with OMB Circular A–110, Subpart C, Section 23. The value of in-kind contributions will be prorated according to the share of total use dedicated to the ATP program. ATP restricts the total value of in-kind contributions that can be used to satisfy the cost share by requiring that such contributions not exceed 30 percent of the non-federal share of the total project costs. ATP shall determine the allowability of matching share costs in accordance with applicable federal cost principles.

(m) The term *person* shall be deemed to include corporations and associations existing under or authorized by the laws of either the United States, the laws of any of the Territories, the laws of any State, or the laws of any foreign country.

(n) The term *Program* means the Advanced Technology Program.

(o) The term *Secretary* means the Secretary of Commerce or the Secretary's designee.

(p) The term *small business* means a business that is independently owned and operated, is organized for profit, and is not dominant in the field of operation in which it is proposing, and meets the other requirements found in 13 CFR part 121.

(q) The term *United States-owned company* means a for-profit organization, including sole proprietors, partnerships, or corporations, that has a majority ownership or control by individuals who are citizens of the United States.

[55 FR 30145, July 24, 1990, as amended at 59 FR 666, 667, Jan. 6, 1994; 62 FR 64684, 64685, Dec. 9, 1997; 63 FR 64413, Nov. 20, 1998]

§295.3 Eligibility of United States- and foreign-owned businesses.

(a) A company shall be eligible to receive an award from the Program only if:

(1) The Program finds that the company's participation in the Program would be in the economic interest of the United States, as evidenced by investments in the United States in research, development, and manufacturing (including, for example, the manufacture of major components or subassemblies in the United States); significant contributions to employment in the United States; and agreement with respect to any technology arising from assistance provided by the Program to promote the manufacture within the United States of products resulting from that technology (taking into account the goals of promoting the competitiveness of United States industry), and to procure parts and materials from competitive suppliers; and

(2) Either the company is a United States-owned company, or the Program finds that the company is incorporated in the United States and has a parent company which is incorporated in a country which affords to United States-owned companies opportunities, comparable to those afforded to any other company, to participate in any joint venture similar to those authorized under the Program; affords the United States-owned companies local investment opportunities comparable to those afforded to any other company; and affords adequate and effective protection for the intellectual property rights of United States-owned companies.

(b) The Program may, within 30 days after notice to Congress, suspend a company or joint venture from continued assistance under the Program if the Program determines that the company, the country of incorporation of the company or a parent company, or the joint venture has failed to satisfy any of the criteria contained in paragraph (a) of this section, and that it is in the national interest of the United States to do so.

(c) Companies owned by legal residents (green card holders) may apply to the Program, but before an award can be given, the owner(s) must either become a citizen or ownership must be transferred to a U.S. citizen(s).

[59 FR 667, Jan. 6, 1994, as amended at 62 FR 64685, Dec. 9, 1997]

§295.4 The selection process.

(a) The selection process for awards is a multi-step process based on the criteria listed in §295.6. Source evaluation boards (SEB) are established to ensure that all proposals receive careful consideration. In the first step, called ''preliminary screening,'' proposals may be eliminated by the SEB that do not meet the requirements of this Part of the annual FEDERAL REGISTER Program announcement. Typical but not exclusive of the reasons for eliminating a proposal at this stage are that the proposal: is deemed to have serious deficiencies in either the technical or business plan; involves product development rather than high-risk R&D; is not industry-led; is significantly overpriced or underpriced given the scope of the work; does not meet the requirements set out in the notice of availability of funds issued pursuant to

§ 295.7; or does not meet the cost-sharing requirement. NIST will also examine proposals that have been submitted to a previous competition to determine whether substantive revisions have been made to the earlier proposal, and, if not, may reject the proposal.

(b) In the second step, referred to as the ''technical and business review,'' proposals are evaluated under the criteria found in § 295.6. Proposals judged by the SEB after considering the technical and business evaluations to have the highest merit based on the selection criteria receive further consideration and are referred to as ''semifinalists.''

(c) In the third step, referred to as ''selection of finalists,'' the SEB prepares a final ranking of semifinalist proposals by a majority vote, based on the evaluation criteria in § 295.6. During this step, the semifinalist proposers will be invited to an oral review of their proposals with NIST, and in some cases site visits may be required. Subject to the provisions of § 295.6, a list of ranked finalists is submitted to the Selecting Official.

(d) In the final step, referred to as ''selection of recipients,'' the Selecting Official selects funding recipients from among the finalists, based upon: the SEB rank order of the proposals on the basis of all selection criteria (§ 295.6); assuring an appropriate distribution of funds among technologies and their applications; the availability of funds; and adherence to the Program selection criteria. The Program reserves the right to deny awards in any case where information is uncovered which raises a reasonable doubt as to the responsibility of the proposer. The decision of the Selecting Official is final.

(e) NIST reserves the right to negotiate the cost and scope of the proposed work with the proposers that have been selected to receive awards. For example, NIST may request that the proposer delete from the scope of work a particular task that is deemed by NIST to be product development or otherwise inappropriate for ATP support.

[63 FR 64413, Nov. 20, 1998]

§ 295.5 Use of pre-proposals in the selection process.

To reduce proposal preparation costs incurred by proposers and to make the selection process more efficient, NIST may use mandatory or optional preliminary qualification processes based on pre-proposals. In such cases, announcements requesting pre-proposals will be published as indicated in § 295.7, and will seek abbreviated proposals (pre-proposals) that address both of the selection criteria, but in considerably less detail than full proposals. The Program will review the pre-proposals in accordance with the selection criteria and provide written feedback to the proposers to determine whether the proposed projects appear sufficiently promising to warrant further development into full proposals. Proposals are neither ''accepted'' or ''rejected'' at the pre-proposal stage. When the full proposals are received in response to the notice of availability of funds described in § 295.7, the review and selection process will occur as described in § 295.4.

[63 FR 64414, Nov. 20, 1998]

§ 295.6 Criteria for selection.

The evaluation criteria to be used in selecting any proposal for funding under this program, and their respective weights, are listed in this section. No proposal will be funded unless the Program determines that it has scientific and technological merit and that the proposed technology has strong potential for broad-based economic benefits to the nation. Additionally, no proposal will be funded that does not require Federal support, that is product development rather than high risk R&D, that does not display an appropriate level of commitment from the proposer, or does not have an adequate technical and commercialization plan.

(a) *Scientific and technological merit (50%).* The proposed technology must be highly innovative. The research must be challenging, with high technical risk. It must be aimed at overcoming an important problem(s) or exploiting a promising opportunity. The technical leverage of the technology must be adequately explained. The research must have a strong potential for

advancing the state of the art and contributing significantly to the U.S. scientific and technical knowledge base. The technical plan must be clear and concise, and must clearly identify the core innovation, the technical approach, major technical hurdles, the attendant risks, and clearly establish feasibility through adequately detailed plans linked to major technical barriers. The plan must address the questions of ''what, how, where, when, why, and by whom'' in substantial detail. The Program will assess the proposing team's relevant experience for pursuing the technical plan. The team carrying out the work must demonstrate a high level of scientific/technical expertise to conduct the R&D and have access to the necessary research facilities.

(b) *Potential for broad-based economic benefits (50%).* The proposed technology must have a strong potential to generate substantial benefits to the nation that extend significantly beyond the direct returns to the proposing organization(s). The proposal must explain why ATP support is needed and what difference ATP funding is expected to make in terms of what will be accomplished with the ATP funding versus without it. The pathways to economic benefit must be described, including the proposer's plan for getting the technology into commercial use, as well as additional routes that might be taken to achieve broader diffusion of the technology. The proposal should identify the expected returns that the proposer expects to gain, as well as returns that are expected to accrue to others, i.e., spillover effects. The Program will assess the proposer's relevant experience and level of commitment to the project and project's organizational structure and management plan, including the extent to which participation by small businesses is encouraged and is a key component in a joint venture proposal, and for large company single proposers, the extent to which subcontractor/subrecipient teaming arrangements are featured and are a key component of the proposal.

[63 FR 64414, Nov. 20, 1998]

§ 295.7 Notice of availability of funds.

The Program shall publish at least annually a FEDERAL REGISTER notice inviting interested parties to submit proposals, and may more frequently publish invitations for proposals in the Commerce Business Daily, based upon the annual notice. Proposals must be submitted in accordance with the guidelines in the ATP Proposal Preparation Kit as identified in the published notice. Proposals will only be considered for funding when submitted in response to an invitation published in the FEDERAL REGISTER, or a related announcement in the Commerce Business Daily.

[63 FR 64414, Nov. 20, 1998]

§ 295.8 Intellectual property rights; publication of research results.

(a)(1) *Patent rights.* Title to inventions arising from assistance provided by the Program must vest in a company or companies incorporated in the United States. Joint ventures shall provide to NIST a copy of their written agreement which defines the disposition of ownership rights among the members of the joint venture, and their contractors and subcontractors as appropriate, that complies with the first sentence of this paragraph. The United States will reserve a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any such intellectual property, but shall not, in the exercise of such license, publicly disclose proprietary information related to the license. Title to any such intellectual property shall not be transferred or passed, except to a company incorporated in the United States, until the expiration of the first patent obtained in connection with such intellectual property. Nothing in this paragraph shall be construed to prohibit the licensing to any company of intellectual property rights arising from assistance provided under this section.

(2) *Patent procedures.* Each award by the Program shall include provisions assuring the retention of a governmental use license in each disclosed invention, and the government's retention of march-in rights. In addition, each award by the Program will contain procedures regarding reporting of subject inventions by the funding Recipient to the Program, including the

subject inventions of members of the joint venture (if applicable) in which the funding Recipient is a participant, contractors and subcontractors of the funding Recipient. The funding Recipient shall disclose such subject inventions to the Program within two months after the inventor discloses it in writing to the Recipient's designated representative responsible for patent matters. The disclosure shall consist of a detailed, written report which provides the Program with the following: the title of the present invention; the names of all inventors; the name and address of the assignee (if any); an acknowledgment that the United States has rights in the subject invention; the filing date of the present invention, or, in the alternative, a statement identifying that the Recipient determined that filing was not feasible; an abstract of the disclosure; a description or summary of the present invention; the background of the present invention or the prior art; a description of the preferred embodiments; and what matter is claimed. Upon issuance of the patent, the funding Recipient or Recipients must notify the Program accordingly, providing it with the Serial Number of the patent as issued, the date of issuance, a copy of the disclosure as issued, and if appropriate, the name, address, and telephone number(s) of an assignee.

(b) *Copyrights:* Except as otherwise specifically provided for in an Award, funding recipients under the Program may establish claim to copyright subsisting in any data first produced in the performance of the award. When claim is made to copyright, the funding recipient shall affix the applicable copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship to the data when and if the data are delivered to the Government, are published, or are deposited for registration as a published work in the U.S. Copyright Office. The funding recipient shall grant to the Government, and others acting on its behalf, a paid up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, perform publicly and display publicly, and for data other than computer software to distribute to the public by or on behalf of the Government.

(c) *Publication of research results:* The decision on whether or not to publish research results will be made by the funding recipient(s). Unpublished intellectual property owned and developed by any business or joint research and development venture receiving funding or by any member of such a joint venture may not be disclosed by any officer or employee of the Federal Government except in accordance with a written agreement between the owner or developer and the Program. The licenses granted to the Government under § 295.8(b) shall not be considered a waiver of this requirement.

[55 FR 30145, July 24, 1990. Redesignated and amended at 59 FR 667, 669, Jan. 6, 1994; 63 FR 64414, Nov. 20, 1998]

§ 295.9 Protection of confidential information.

As required by section 278n(d)(5) of title 15 of the United States Code, the following information obtained by the Secretary on a confidential basis in connection with the activities of any business or joint research and development venture receiving funding under the program shall be exempt from disclosure under the Freedom of Information Act—

(1) Information on the business operation of any member of the business or joint venture;

(2) Trade secrets possessed by any business or any member of the joint venture.

[55 FR 30145, July 24, 1990. Redesignated at 59 FR 667, Jan. 6, 1994]

§ 295.10 Special reporting and auditing requirements.

Each award by the Program shall contain procedures regarding technical, business, and financial reporting and auditing requirements to ensure that awards are being used in accordance with the Program's objectives and applicable Federal cost principles. The purpose of the technical reporting is to monitor ''best effort'' progress toward overall project goals. The purpose of the business reporting system is to monitor project performance against the Program's mission as required by

the Government Performance and Results Act (GPRA) mandate for program evaluation. The audit standards to be applied to ATP awards are the ''Government Auditing Standards'' (GAS) issued by the Comptroller General of the United States (also known as yellow book standards) and the ATP program-specified audit guidelines. The ATP program-specific audit guidelines include guidance on the number of audits required under an award. In the interest of efficiency, the recipients are encouraged to retain their own independent CPA firm to perform these audits. The Department of Commerce's Office of Inspector General (OIG) reserves the right to conduct audits as deemed necessary and appropriate.

[62 FR 64686, Dec. 9, 1997. Redesignated at 63 FR 64415, Nov. 20, 1998]

§ 295.11 Technical and educational services for ATP recipients.

(a) Under the Federal Technology Transfer Act of 1986, the National Institute of Standards and Technology of the Technology Administration has the authority to enter into cooperative research and development agreements with non-Federal parties to provide personnel, services, facilities, equipment, or other resources except funds toward the conduct of specified research or development efforts which are consistent with the missions of the laboratory. In turn, the National Institute of Standards and Technology has the authority to accept funds, personnel, services, facilities, equipment and other resources from the non-Federal party or parties for the joint research effort. Cooperative research and development agreements do not include procurement contracts or cooperative agreements as those terms are used in sections 6303, 6304, and 6305 of title 31, United States Code.

(b) In no event will the National Institute of Standards and Technology enter into a cooperative research and development agreement with a recipient of awards under the Program which provides for the payment of Program funds from the award recipient to the National Institute of Standards and Technology.

(c) From time to time, ATP may conduct public workshops and undertake other educational activities to foster the collaboration of funding Recipients with other funding resources for purposes of further development and commercialization of ATP-related technologies. In no event will ATP provide recommendations, endorsements, or approvals of any ATP funding Recipients to any outside party.

[55 FR 30145, July 24, 1990. Redesignated at 59 FR 667, Jan. 6, 1994. Redesignated and amended at 63 FR 64415, Nov. 20, 1998]

Subpart B—Assistance to United States Industry-Led Joint Research and Development Ventures

§ 295.20 Types of assistance available.

This subpart describes the types of assistance that may be provided under the authority of 15 U.S.C. 278n(b)(1). Such assistance includes but is not limited to:

(a) Partial start-up funding for joint research and development ventures.

(b) A minority share of the cost of joint research and development ventures for up to five years.

(c) Equipment, facilities and personnel for joint research and development ventures.

§ 295.21 Qualifications of proposers.

Subject to the limitations set out in § 295.3, assistance under this subpart is available only to industry-led joint research and development ventures. These ventures may include universities, independent research organizations, and governmental entities. Proposals for funding under this Subpart may be submitted on behalf of a joint venture by a for-profit company or an independent research organization that is a member of the joint venture. Proposals should include letters of commitment or excerpts of such letters from all proposed members of the joint venture, verifying the availability of cost-sharing funds, and authorizing the party submitting the proposal to act on behalf of the venture with the Program on all matters pertaining to the proposal. No costs shall be incurred under an ATP project by the joint venture members until such time as a

joint venture agreement has been executed by all of the joint venture members and approved by NIST. NIST will withhold approval until it determines that a sufficient number of members have signed the joint venture agreement. Costs will only be allowed after the execution of the joint venture agreement and approval by NIST.

[63 FR 64415, Nov. 20, 1998]

§ 295.22 Limitations on assistance.

(a) An award will be made under this subpart only if the award will facilitate the formation of a joint venture or the initiation of a new research and development project by an existing joint venture.

(b) The total value of any in-kind contributions used to satisfy the cost sharing requirement may not exceed 30 percent of the non-federal share of the total project costs.

[62 FR 64687, Dec. 9, 1997]

§ 295.23 Dissolution of joint research and development ventures.

Upon dissolution of any joint research and development venture receiving funds under these procedures or at a time otherwise agreed upon, the Federal Government shall be entitled to a share of the residual assets of the joint venture proportional to the Federal share of the costs of the joint venture as determined by independent audit.

§ 295.24 Registration.

Joint ventures selected for funding under the Program must notify the Department of Justice and the Federal Trade Commission under the National Cooperative Research Act of 1984. No funds will be released prior to receipt by the Program of copies of such notification.

[63 FR 64415, Nov. 20, 1998]

§ 295.25 Special rule for the valuation of transfers between separately-owned joint venture members.

(a) *Applicability*. This section applies to transfers of goods, including computer software, and services provided by the transferor related to the maintenance of those goods, when those goods or services are transferred from one joint venture member to other separately-owned joint venture members.

(b) *Rule.* The greater amount of the actual cost of the transferred goods and services as determined in accordance with applicable Federal cost principles, or 75 percent of the best customer price of the transferred goods and services, shall be deemed to be allowable costs; provided, however, that in no event shall the aggregate of these allowable costs exceed 30 percent of the non-Federal share of the total cost of the joint research and development program.

(c) *Definition.* The term ''best customer price'' shall mean the GSA schedule price, or if such price is unavailable, the lowest price at which a sale was made during the last twelve months prior to the transfer of the particular good or service.

[62 FR 64687, Dec. 9, 1997]

Subpart C—Assistance to Single-Proposer U.S. Businesses

§ 295.30 Types of assistance available.

This subpart describes the types of assistance that may be provided under the authority of 15 U.S.C. 278n(b)(2). Such assistance includes but is not limited to entering into cooperative agreements with United States businesses, especially small businesses.

[59 FR 670, Jan. 6, 1994]

§ 295.31 Qualification of proposers.

Awards under this subpart will be available to all businesses, subject to the limitations set out in §§ 295.3 and 295.32.

[62 FR 64687, Dec. 9, 1997]

§ 295.32 Limitations on assistance.

(a) The Program will not directly provide funding under this subpart to any governmental entity, academic institution or independent research organization.

(b) For proposals submitted to ATP after December 31, 1997, awards to large businesses made under this subpart shall not exceed 40 percent of the total project costs of those awards in any year of the award.

(c) Awards under this subpart may not exceed $2,000,000, or be for more than three years, unless the Secretary provides a written explanation to the authorizing committees of both Houses of Congress and then, only after thirty days during which both Houses of Congress are in session. No funding for indirect costs, profits, or management fees shall be available for awards made under this subpart.

(d) The total value of any in-kind contributions used to satisfy a cost sharing requirement may not exceed 30 percent of the non-federal share of the total project costs.

[62 FR 64687, Dec. 9, 1997]

PARTS 296—299 [RESERVED]